Supreme Court, U.S.
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No. 02-

IN THE

Supreme Court of the United States

DEY, L.P. and DEY, INC.,

Petitioners,

v.

ABBOTT LABORATORIES and
MITSUBISHI-TOKYO PHARMACEUTICALS, INC.
(formerly known as Tokyo Tanabe Co., Ltd.),

Respondents.

**ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

A patent holder may not extend the doctrine of equivalents to recapture subject matter that was foreseeable and expressly disclosed, but unclaimed. The United States Court of Appeals for the Federal Circuit recently reaffirmed this principle in its *en banc* decision in *Johnson & Johnston Associates Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002). Less than a month later, in this case, a panel of the same court applied the doctrine of equivalents to claim subject matter that was foreseeable and expressly disclosed, but that the patent holder had deliberately not claimed in his patent. In so doing, the Federal Circuit ignored the basic precept that "a patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 122 S. Ct. 1831, 1837 (2002).

This case, therefore, raises the following questions of critical importance to patent holders and the public:

1. May foreseeable subject matter that is expressly disclosed in a patent, but not claimed by the patent holder, be reclaimed by the patent holder under the doctrine of equivalents?

2. Should there be an inflexible bar to the use of statements made during the prosecution of one patent to construe the claims of an improvement patent that derived from the same subject matter as the first patent, expressly referenced the subject matter of the first patent, was co-pending before the same patent examiner, and had a common inventor?

3. May a patent holder unilaterally extend his patent monopoly over subject matter that he previously had disclosed but did not claim, thereby depriving the public of meaningful notice of what the patent holder owns, and enabling the patent holder to restrain competition that does not infringe the claims of the patent.

4. Should this case be remanded for further consideration in light of this Court's recent decision in *Festo v. Shoketsu Kinzoku Kabushiki Co. Ltd.*, 122 S. Ct. 1831 (2002)?

PARTIES TO THE PROCEEDING

Pursuant to Rule 29.6, Petitioners inform the Court that Dey, Inc. is the general partner to Dey, L.P., a limited partnership formed under the laws of the Delaware. EMD, Inc., Merck S.A., and Merck KGaA are all direct or indirect parent corporations of Dey, Inc. Merck KGaA is a 26% publicly held German company, with 74% controlled by a German partnership called E.Merck. There are no publicly held companies that own 10% or more of the stock of Dey, L.P. or Dey, Inc.

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OPINIONS BELOW

The Federal Circuit's decision vacating the summary judgment of the district court and remanding the case is reported at 287 F.3d 1097 (Fed. Cir. 2002). The district court's May 18, 2001 opinion and order granting Dey's motion for summary judgment (App. 23a-29a), is unreported.

STATEMENT OF JURISDICTION

The Federal Circuit entered its judgment on April 23, 2002. The Federal Circuit denied a timely petition for a rehearing and rehearing *en banc* on June 14, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article 1, section 8, clause 8 of the Constitution provides:

> Congress shall have the power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Respective Writings and Discoveries.

35 U.S.C. § 271(a) provides:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

STATEMENT OF THE CASE

The decision of the Federal Circuit Court of Appeals in this patent infringement case (the "Panel Decision") sends contradictory messages to the public regarding the extent to which the claims in a patent truly define the boundaries of a patent monopoly. Not only does the Panel Decision conflict with decisions of this Court, but it exposes unresolved conflicts within the Federal Circuit as to the meaning of the doctrine of equivalents and surrender. Specifically, in *Johnson & Johnston Associates v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002), the Federal Circuit, sitting *en banc*, reconciled two conflicting schools of judicial thought by holding that a patent holder cannot extend the doctrine of equivalents to claim subject matter that was foreseeable and expressly disclosed, but unclaimed. Nevertheless, one month later, the Panel Decision applied the doctrine of equivalents to allow a patent holder to claim subject matter that was not only foreseeable and expressly disclosed, but expressly disclaimed.

The Panel Decision reveals further conflict within the Federal Circuit, as it has resulted in contradictory decisions involving the same patents-in-suit. In *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001), a panel of the Federal Circuit relied on limiting statements made during the prosecution of U.S. Patent No. 4,338,301 ("the '301 patent") to interpret the claims of an improvement of the '301 patent, U.S. Patent No. 4,397,839 ("the '839 patent"). The Panel Decision, however, held that the relationship between the two patents was insufficient to allow the arguments made during prosecution of the '301 patent, and relied upon by the court in *Forest Laboratories*, to be equally applicable to the claims of the '839 patent.

A. Factual Background

In March 2000, Abbott Laboratories ("Abbott") sued Dey, L.P. ("Dey"), alleging infringement of the '301 and '839 patents. The '301 patent issued on July 6, 1982, and expired on May 21, 2000. The '839 patent, an improvement patent that was co-pending before the same examiner with the '301 patent, issued on August 9, 1983 and, due to an extension granted under 35 U.S.C. § 156, expires on July 1, 2005. Mitsubishi-Tokyo Pharmaceuticals, Inc. ("Mitsubishi"), as successor to Tokyo Tanabe, the owner of the two patents, licensed them to Abbott in the United States on an exclusive basis.

The '301 patent describes a lung surfactant useful for treating neonatal respiratory distress syndrome (RDS). Surfactant coats the alveoli of the lungs, reducing the surface tension within the alveoli, allowing them to expand and contract easily during respiration. Premature babies often do not produce enough surfactant, requiring the baby to exert so much effort in breathing that the baby dies of exhaustion. The surfactants used to treat RDS, naturally derived from mammalian lung extract, are primarily comprised of phospholipids and other ingredients such as protein, neutral lipids, and water.

The claims submitted with the original application for the '301 patent were narrowly drawn to specific ranges of the components of the "surface active material". These initial claims were at first rejected as being "prima facie obvious" in view of the prior art. (JA2355.)[1] The Patent and Trademark

1. References to "JA" are to the Joint Appendix filed by the Appellants to the Court of Appeals for the Federal Circuit in connection with this case on September 17, 2001.

Office (PTO) examiner finally allowed the claims after the applicant asserted that "only a surface active material having the chemical composition claimed and disclosed . . . has the property of rapid spreading and of ultra-alveolar surface tension reduction." (JA2366-JA2367.) Consequently, the '301 patent claimed a specific range for each of the following six components: phospholipid, neutral lipid, total cholesterol, carbohydrate, protein and water. (JA1140-JA1141.) In particular, the '301 patent claimed a phospholipid content range between 75.0% and 95.5%.

The '839 patent was allegedly the result of further experimentation by one of the inventors of the '301 patent on the surface active material that had formed the basis for the '301 patent. The '839 patent stated that the results achieved by the surface active material could be "enhanced by increasing the relative amount or content of free fatty acids from the content claimed in the '301 patent to 1.0%-27.7% based on the total weight" of the surface active material. (JA1118.) Consequently, the '839 patent claims a free fatty acid range between 1.0% and 27.7% and a phospholipid range between 68.6% and 90.7%. (JA1126.) Thus, in the '839 patent application, the maximum phospholipid content was expressly reduced from 95.5% in the original compound to 90.7%.

The examples in the '839 patent stress the importance of the addition of free fatty acid and teach the importance of lowering the phospholipid content to within the claimed ranges. Specifically, Example 3 of the '839 patent instructs that, given a surface active material with a phospholipid content of 92.8%, additional ingredients should be added until the phospholipid content of the composition falls within the exact level specified by the claims, i.e., 68.6% to 90.7%.

Reading Example 3 together with Table VII (column 3), all of the compositional elements of claim 1 of the patent are present. Thus, Example 3 expressly teaches that the phospholipid content must be lowered to no greater than 90.7%. (JA1124-JA1125.) The Federal Circuit ignored this point and, in doing so, rendered a decision in the present case that is at odds with other Federal Circuit decisions on issues of surrender and public notice.

B. Procedural Background

In 1991, pursuant to the exclusive license from Mitsubishi on the two patents, Abbott began to market the drug Survanta®, an artificial bovine based lung surfactant. In 1999, Dey received approval from the FDA to market its own lung surfactant, Curosurf®, which is entirely derived from a porcine lung extract. Curosurf® paste (the precursor material to Curosurf®) is characterized by a very high phospholipid content, a negligible amount of (or zero) free fatty acid, and the absence of carbohydrate.

On March 21, 2000, Abbott sued Dey for infringement of the '301 and '839 patents. Abbott asserted infringement of claims 1, 9, and 12-15 of the '839 patent. Claim 1, which recites the claimed ranges of the surface active material, including the upper phospholipid limit of 90.7%, is the only independent claim of the '839 patent. Dependent claims of the patent cannot be infringed unless the independent claim is infringed.

On May 19, 2000, Abbott moved for a preliminary injunction. Because the '301 patent was to expire on May 25, 2000, Abbott sought a preliminary injunction only with regard to the '839 patent. During an evidentiary hearing,

Abbott submitted evidence that its own tests on Curosurf® (the Dey product) demonstrated that one lot of Dey's Curosurf® paste contained 95.4% phospholipid, while the other lot of Curosurf paste® had a phospholipid content of 91.8%. (JA324; JA480.) Both of these measurements exceed the upper range of the phospholipid content claimed in Claim 1 of the '839 patent, namely, 90.7%. Thus, Abbott conceded that it could not prove literal infringement of Claim 1 of the '839 patent. The only issue, then, was whether Abbott could demonstrate that it would be able to prove infringement under the doctrine of equivalents.

On July 25, 2000, the district court denied Abbott's motion for a preliminary injunction. The district court held that Abbott had introduced evidence to suggest that "a phospholipid percentage as high as 99.99% would have functioned the same way, thereby effectively and improperly reading out the phospholipid range limitation altogether," (App. 35a) (citing *Warner-Jenksinson Co. v. Hilton-Davis Chem. Co*, 520 U.S. 17, 29 (1997)). Moreover, the district court held that extending the phospholipid range to an equivalent of the phospholipid ranges of Curosurf® created a hypothetical claim anticipated by the prior art (i.e., covered by the 95.5% phospholipid limit claimed by the '301 patent) that would have been disallowed by the PTO. (App. 36a.)

The district court stressed that it was not the mere existence of the free fatty acid that made the material disclosed in the '839 patent unique over the '301 patent, but the increase in the free fatty acid content. As any increase in the proportion of free fatty acid required a corresponding decrease in the proportion of the material's other components, the court stated that "the change in the percentages and the ratio among the various components must have been

significant to the patent examiner." (App. 38a.) Consequently, the district court held that "it has no reason to believe the claim would have been allowed without the alterations made to the percentage ranges of both free fatty acid and phospholipid." (App. 38a.) Abbott's request for a preliminary injunction was therefore denied.

Soon after the district court's decision, Dey filed a motion for summary judgment dismissing Abbott's claims of infringement. The district court chose to stay the motion pending the review of its decision on the preliminary injunction motion by the Federal Circuit Court of Appeals. The parties had fully briefed the appeal of the preliminary injunction denial and the court of appeals had assigned an oral argument date of June 7, 2001, when the Federal Circuit decided *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001), which addressed the same patents as are at issue here.

In *Forest Laboratories*, the Federal Circuit held that the doctrine of equivalents did not extend to the water claim limitation of the '839 and '301 patents. Abbott argued that Forest's lung surfactant, Infasurf®, infringed the '839 and '301 patents and attempted to apply the doctrine of equivalents to the water limitation of each patent. The Federal Circuit held that "arguments made during prosecution lead to the conclusion that the claims should be limited to their literal scope." *Id.* at 1313, 1314. In particular, the Federal Circuit cited the patentee's argument to the PTO during the prosecution of the '301 patent "that only a surface-active material having the chemical composition claimed and disclosed . . . [has] the property of rapid spreading and of ultra-alveolar surface tension reduction." *Id.* at 1314. According to the court, this statement was "an unmistakable

assertion made to the PTO in support of patentability." *Id.* Based on this statement made during the prosecution of the'301 patent, the Court limited the claims of both the '839 and the '301 patents to their literal scope and declined to apply the doctrine of equivalents to the water limitation of claim 1 of both the '839 and the '301 patents.

In light of the Federal Circuit's decision in *Forest Laboratories*, Dey renewed its motion for summary judgment. The district court granted Dey's motion for summary judgment on May 18, 2001. The district court held that, as a matter of law, in light of the specification and claims of the '839 patent and limiting statements made during the prosecution of the '301 patent, the patentee had surrendered the phospholipid range above 90.7%. In particular, the district court pointed to the patentee's assertion in the specifications of the '839 patent that the properties of the surface active material were enhanced by the addition of free fatty acid as evidence that the chemical composition of the patent was significant and the changes made in the composition were significant. According to the district court, when "the patentee chose to include specific percentage ranges for each chemical component in the surface active material . . . he created a record that fairly notified the public that he was surrendering the right to exclude material comprised of even the same component of different percentages." (App. 28a.) As a result, the district court held that Abbott cannot "recapture the surrendered subject matter through the doctrine of equivalents; nor can they recapture through the doctrine of equivalents the higher phospholipid percentage surrendered from the '301 patent with the issuance of the '839 patent." (App. 28a.)

Following the district court's grant of summary judgment, the court of appeals dismissed Abbott's appeal of the denial of its motion for preliminary injunction as moot. Abbott subsequently appealed the district court's order granting summary judgment to the Federal Circuit.[2]

On April 23, 2002, the Federal Circuit vacated the district court judgment and remanded for further proceedings. Contrary to its holding in *Forest*, the Federal Circuit held that "the relationship, if any, between the '839 and '301 patents is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent." (App. 13a.) In addition, without addressing the district court's finding that Abbott had created a record in the specifications of the '839 patent that limited to specific proportions the components in the claims of the '839 patent, the court of appeals held that Abbott did not surrender subject matter by including specific numeric ranges in its claims.

On May 7, 2002, Dey submitted a timely petition for rehearing and rehearing *en banc* to the Federal Circuit. The Federal Circuit denied Dey's petition on June 14, 2002. (App. 39a-40a.)

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2. Notably, the district court granted summary judgment of non-infringement on both the '839 and the '301 patents. In its request for relief to the Court of Appeals, Abbott sought to vacate the district court's judgment in its entirety. However, Abbott presented no argument — either in response to Dey's motion for summary judgment or in its appeal — that Curosurf® infringed the now expired '301 patent either literally or under the doctrine of equivalents. Abbott's own measurements of Dey's Curosurf® show that Curosurf® does not literally infringe the '301 patent: Abbott's measurement of the neutral lipids in Curosurf® fell outside the range claimed in the '301 patent for neutral lipids. Further, the file history of the '301 patent expressly states that the '301 patent is limited to the claimed ranges.

REASONS FOR GRANTING THE WRIT

Petitioner Dey seeks review of the decision below (the "Panel Decision") because (1) it is a radical departure from, and in direct conflict with, settled law in the Federal Circuit; (2) it conflicts with this Court's opinions in *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17 (1997), and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 122 S. Ct. 1831 (2002); and (3) it eviscerates the policy that "a patent holder should know what he owns and the public should know what he does not." *Festo*, 122 S. Ct. 1831, 1836 (2002).

The Panel Decision directly conflicts with previous decisions of the Federal Circuit, most notably *Johnson & Johnston Associates Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (*en banc*), and *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001). In *Johnson* and *Forest Laboratories* (a decision that addressed the same patents as are at issue here), the Federal Circuit unambiguously held that subject matter that is disclosed (and *a fortiori* foreseeable) but not claimed in a patent is dedicated to the public and *may not* be reclaimed by the patent holder. This is in stark contrast to the Panel Decision, which holds that subject matter disclosed but not claimed in a patent *may* be reclaimed by the patent holder under the doctrine of equivalents. The decisions cannot be reconciled, leaving a zone of uncertainty facing patent holders and the public.

The Panel Decision also conflicts with the decisions of this Court in *Festo* and *Warner-Jenkinson*. Because this Court's decision in *Festo* was issued after the Panel Decision, and after submission of the Petition for Rehearing *en banc*, *Festo* was not considered by the court below. In deviating from the

teachings of *Warner-Jenkinson*, and without the benefit of *Festo's* elucidation of the doctrine of equivalents, the Panel Decision destabilizes the delicate balance between a patent holder's right to protect its monopoly and the right of others to create, promote and commercialize a non-infringing product. *See Festo*, 122 S. Ct. at 1837 (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989)). At the very least, the Panel Decision should be vacated and remanded for reconsideration in light of *Festo*.

The Panel Decision threatens to create serious confusion in the law governing the boundaries of a patent holder's temporary monopoly. In lieu of following its own *en banc* precedent in *Johnson*, the Federal Circuit resurrected the holding of a prior case, *YBM Magnex, Inc. v. International Trade Commission*, 145 F.3d 1317 (Fed. Cir. 1998), which had been explicitly overruled in *Johnson*. Given the Federal Circuit's strange departure from precedent, this Court should grant *certiorari* to restore a measure of confidence that a patent provides meaningful notice of what a patent holder owns and what he does not.

I. Certiorari Should Be Granted Because the Decision Below Is In Direct Conflict With Prior Decisions Of The Federal Circuit, Including a Decision Involving the Same Patents at Issue

The Federal Circuit has exclusive jurisdiction over "an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on [28 U.S.C. §] 1338. . . ." 28 U.S.C. § 1295(a)(1). Section 1338(a) provides that "[t]he district courts shall have original jurisdiction of any civil action

arising under any Act of Congress relating to patents. . . ."[3] The Federal Circuit thus is the principal arbiter of patent-related cases among the federal circuit appellate courts: it has jurisdiction of an appeal from a district court where the patent issue arose in the complaint; and it has jurisdiction of an appeal from a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office with respect to patent applications and interferences, at the instance of an applicant for a patent or any party to a patent interference. 28 U.S.C. §§ 1295(a)(1), (4). As a result, two diametrically opposed decisions of the Federal Circuit create a conflict of the same magnitude as a conflict between two circuits in non-patent cases. *Cf. Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 128 (1942) (granting *certiorari* in part because industry affected by the patent was located in one circuit so that litigation in other circuits resulting in a conflict was unlikely to occur).[4]

1. The Federal Circuit recently resolved two conflicting lines of jurisprudence on the issue of unclaimed subject matter in *Johnson*. Surprisingly, less than a month after that *en banc* decision, the Panel deviated from the instruction of

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3. This Court recently held in *Holmes Group Inc. v. Vornado Air Circulation Systems, Inc.*, 122 S. Ct. 1889 (2002), that the Federal Circuit could not properly assert jurisdiction where the patent issue arose as part of a counterclaim.

4. Nor should the procedural posture of the case (reversal of a summary judgment that had dismissed the case) discourage this Court from granting this Petition. When a ruling as a matter of law is reversed in a manner that threatens to confuse the law with respect to critical issues, this Court previously has not hesitated to accept review. *See, e.g., Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995); *Mobil Oil Exploration and Producing Southeast, Inc. v. United States*, 530 U.S. 604 (2000).

the majority of the Federal Circuit in this case. The patent at issue in *Johnson* (the " '050 patent") related to manufacture of printed circuit boards. The circuit boards were composed of thin sheets of copper foil, which could be damaged easily when handled manually. The '050 patent claimed an assembly using aluminum substrate attached to the circuit board, which would prevent damage during manual handling. The specification in the patent (but not the claim) stated that "[w]hile aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys, may be used." *Johnson*, 285 F.3d at 1050. The defendant, RES, manufactured an assembly using a sheet of steel instead of aluminum substrate, and the patent holder sued for infringement.

On appeal from a jury verdict of willful infringement, the Federal Circuit, sitting *en banc*, reversed. After reviewing the two precedents most applicable to the case, *Maxwell v. Baker, Inc.*, 86 F.3d 1098 (Fed. Cir. 1996), and *YBM Magnex v. International Trade Commission*, 145 F.3d 1317 (Fed. Cir. 1998), as well as prior decisions of this Court, the *en banc* court held that the patent holder must be barred from using the doctrine of equivalents to recover unclaimed subject matter disclosed in a specification.

The Federal Circuit stressed that "when a patent drafter discloses but declines to claim subject matter, . . . this action dedicates that unclaimed subject matter to the public." *Johnson*, 285 F.3d at 1054. The Federal Circuit relied predominantly on *Maxwell*, where the patent holder, Maxwell, had claimed a system for fastening a pair of shoes using tabs between the inner and outer soles. Maxwell had disclosed in the specification, but did not claim, fastening tabs that could be stitched into the lining of the shoes.

Johnson, 285 F.3d at 1051 (citing *Maxwell*, 86 F.3d at 1101-02). The *Maxwell* panel held that as a matter of law, the doctrine of equivalents could not be used to support an allegation of infringement based on the disclosed but unclaimed subject matter. *Id.*

The *Johnson* court compared *Maxwell* to *YBM Magnex*. According to the *Johnson* court, *YBM Magnex* "purported to limit *Maxwell* to situations where the patent holder discloses an unclaimed alternative distinct from the claimed invention." *Johnson*, 285 F.3d at 1052.

The Federal Circuit in *Johnson* concluded, *en banc*, that it had been right in *Maxwell* and wrong in *YBM Magnex*. It refused to limit *Maxwell* in the manner prescribed by *YBM Magnex*, and held that Johnson was barred from using the doctrine of equivalents to reclaim subject matter that had been surrendered. The Federal Circuit could not have been more clear:

> Having disclosed without claiming the steel substrates, Johnston cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel. Thus, Johnston cannot assert the doctrine of equivalents to cover the disclosed but unclaimed steel substrate.

And the court rejected the prior panel decision in *YBM Magnex*:

> To the extent that YBM Magnex conflicts with this holding, this *en banc* court now *overrules* that case.

Id. at 1055 (emphasis added). The present case is *a fortiori* because the substance as to which Abbott seeks to apply the

doctrine of equivalents was not only disclosed and unclaimed — it was disclosed and expressly disclaimed. For instance, in Example 3 of the '839 patent, the inventor intentionally lowered the phospholipid content from 92.8% to 90.7% by adding neutral lipid (discussed *infra*) (JA1124); moreover, the inventor chose to claim a phospholipid range up to 90.7% in the '839 patent (JA1126), expressly lowering it from the maximum phospholipid content claimed in the '301 patent, 95.5%. (JA1140-JA1141.)

Another important precedent ignored by the Panel Decision is *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997), on which the Federal Circuit had relied in *Johnson*. *Sage* goes further than *Johnson*, holding that a feature obvious from the face of the patent, even if not expressly disclosed, bars the application of the doctrine of equivalents as a basis for infringement.

Sage argued that the defendant had infringed its patent for a container that allowed a user to deposit hazardous medical waste without touching other waste in the container. The alleged infringing device also was a container for the deposit of hazardous waste, but with constrictions in a location different from that claimed in Sage's patent. *Id.* at 1422. The Federal Circuit held that there was no infringement under the doctrine of equivalents because "a skilled patent drafter would foresee the limiting potential of [Sage's claim]." *Id.* at 1425. Thus, the court rejected the allegation of infringement under the doctrine of equivalents — not because the subject matter was disclosed and not claimed, but simply because the subject matter was foreseeable and could have been claimed by one skilled in the art. *Id.*; *see also Sontag Chain Stores Co. v. National Nut Co.*, 310 U.S. 281, 293 (1940) (quoting *Miller v. Brass Co.*, 104 U.S.

350, 352 (1881)) ("It is now accepted doctrine that the 'claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public to that which is not claimed.' ").

Anticipating this Court's opinions in *Warner-Jenkinson* and *Festo*, the *Sage* court recognized that its holding placed a significant burden on patent holders drafting claims. However,

> [g]iven a choice of imposing the higher costs of careful prosecution on patent holders, or imposing the costs of foreclosed business activity on the public at large, this court believes the costs are properly imposed on the group best positioned to determine whether or not a particular invention warrants investment at a higher level, that is, the patent holders.

Id. at 1425. Thus *Sage*, never overruled, and cited favorably by the Federal Circuit sitting *en-banc* in *Johnson*, flatly contradicts the Panel Decision, which allows a claim for infringement by subject matter that was clearly foreseeable (in this case, disclosed and expressly disclaimed in the specifications) and that could have been claimed by the patent holder.

2. The decision below also is inconsistent with the Federal Circuit's decision in *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001), which involved the same '839 and '301 patents. In *Forest Laboratories*, the Federal Circuit found that in light of the close relationship between the two patents, the file history

of the '301 patent created an estoppel with respect to the '839 patent. It explained that the claims of the '839 patent "should be limited to their literal scope," as a result of "arguments made during prosecution" in the '301 file history. *Id.* at 1313-14. The Panel Decision, on the other hand, holds that the "relationship, if any, between the '839 and '301 patent is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent." (App. 13a.)

The Panel Decision is in direct conflict with the Federal Circuit's decision on the same issue in *Forest Laboratories*. The undisputed facts present in both cases are that the claims of the '839 patent were narrowly drawn to reflect an incremental improvement over the '301 patent, the inventor of the '839 patent was one of the co-inventors of the '301 patent, the filing dates were only a few months apart, and the '839 patent expressly refers to and relies on the subject matter of the '301 patent. *Forest Laboratories* correctly held that the limiting statements made during prosecution of the '301 patent were relevant to construction of the claims of the '839 patent, and that the patent holder was estopped from asserting infringement under the doctrine of equivalents with respect to both the '301 and the '839 patents based on statements made during prosecution of the '301 patent. The Panel Decision holds otherwise. The two decisions cannot be reconciled.

3. Inexplicably, the Panel ignored *Johnson*, *Maxwell* and *Sage*, and misread *Forest Laboratories*, even though all of these cases had been cited in the Petitioner's pleadings in the Federal Circuit. The subject matter that Abbott surrendered, but now seeks to claim under the doctrine of equivalents, was obvious from the face of the '839 patent, as

it had been in *Sage*; and was disclosed in the specification of the '839 patent, as it had been in *Johnson* and *Maxwell.* Yet, in contravention of these binding precedents, the Panel Decision permits the application of the doctrine of equivalents. The Federal Circuit's error is particularly striking in the instant case, because the surrendered subject matter was foreseeable, disclosed and effectively *disclaimed* in the '839 patent.

Specifically, Example 3 of the '839 patent discloses an animal lung extract made in accordance with the teachings of that patent. (JA 1124, Col. 13, lines 14-35). In Example 3, the initial extract "had a phospholipid content of 92.8%, a neutral fat content of 0.2%, and a free fatty acid content of 1.5%," and the other components recited in the claims. (JA 1124, Col. 13, lines 24-26, and Table VII, column 3). This 92.8% phospholipid content is greater than the highest amount recited in the claims of the '839 patent, namely 90.7%. (*Id.*, Col. 13, line 25; and Table VII referencing Example 3). In Example 3, the inventor intentionally instructs to lower the amount of phospholipid (down from 92.8%) in that material by adding additional ingredients, including 1.0g of tripalmitoylglycerol (a neutral lipid) and 0.7g of tristearoylglycerol (a neutral lipid), so that the phospholipid content fell within the exact level recited in the claims (90.7%). (*Id.*, Col. 13, lines 29-36). The inventor's intentional acts to bring the phospholipid content within the claimed range reflect his considered decision that a material with greater than 90.7% phospholipid content was not worth claiming in his patent, or could not be claimed without adversely affecting patentability over prior art.

As the Federal Circuit has stated: "in order to determine what subject matter an applicant surrenders during

prosecution, [the test is] 'whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter.' " (App. 12a), (quoting *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373, 1377 (Fed Cir. 1999). In this case, the record plainly demonstrates an affirmative surrender, of disclosed and foreseeable subject matter, to insure patentability over prior art — all of the factors that the Federal Circuit found compelling in *Johnson*, *Maxwell*, *Sage* and *Forest*. Yet, the Federal Circuit would allow the doctrine of equivalents to apply in this case. The irreconcilable conflict created by the Panel Decision urgently requires clarification by this Court.

II. Certiorari Should Be Granted Because The Decision Below Conflicts With Relevant Decisions of this Court

This Court has recognized the importance of the doctrine of equivalents to patent holders and the public by issuing two decisions clarifying the scope of the doctrine in the past five years: *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17 (1997) and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 122 S. Ct. 1831 (2002). One of the core holdings in both decisions is a test of foreseeability: if a patent holder could have written his claims to encompass the disputed equivalent, he should have done so. The Panel Decision, in a case where the alleged equivalent was foreseeable, unclaimed *and* affirmatively surrendered, would allow the patent holder to reclaim the territory abandoned, thereby foreclosing legitimate competition. The clear conflict with this Court's holdings disrupts the expectations created by *Warner-Jenkinson* and *Festo*.

1. The test of foreseeability, anticipated in *Sage* and *Johnson*, was embraced in *Warner-Jenkinson* and, even more explicitly, in *Festo*. In *Warner-Jenkinson*, the patent at issue involved a filtration process. The inventors, Hilton-Davis, had limited their claims to a pH range between 6 and 9. The upper limit (9) was claimed specifically to distinguish the patent from prior art which had disclosed a process using a pH greater than 9. There was a dispute as to why the lower limit had been claimed. Warner-Jenkinson used a process with a pH of 5, clearly below the lower limit of the patent.

While this Court refused to abolish the doctrine of equivalents, the Court voiced its concern that the doctrine of equivalents "has taken on a life of its own, unbounded by the patent claims," *Warner-Jenkinson*, 520 U.S. at 28-29, and cautioned against overly broad use of the doctrine. The doctrine of equivalents should not be used to effectively eliminate an element in its entirety, because "each element contained in a patent claim is deemed material to defining the scope of a patented invention. . . ." *Id.* In order to further prevent patent holders from unduly extending the scope of their patent monopolies, this Court placed the burden squarely on the patent holder to rebut the presumption that when a patent holder chooses to narrow a claim, his amendment is substantive and is made for the purpose of making his invention patentable. *Id.* at 33.

2. When *Festo* reached this Court for the second time,[5] the Court unanimously opted for a doctrine of equivalents that was flexible, but constrained, so as not to extend a patent

5. This Court considered a first Petition for Certiorari in *Festo* in 1996. At that time, the Court vacated the Federal Circuit's decision finding infringement under the doctrine of equivalents for reconsideration in light of *Warner-Jenkinson*.

beyond its proper scope. This Court held that the patent holder could be estopped from asserting the doctrine of equivalents as a result of any substantive amendment, not just one made to avoid prior art, and that the burden was on the patent holder to prove that the amendment was not made for a reason that would give rise to an estoppel. Importantly, this Court focused on the policy that the patent holder cannot reclaim foreseeable subject matter previously surrendered by asserting the doctrine of equivalents. Prosecution history, the Court found, is one way of showing that "the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter." 122 S. Ct. at 1831. As this Court has previously acknowledged, prosecution history estoppel has its roots in general notions of equitable estoppel — a well established rule that a plaintiff may not reclaim what he has knowingly waived. *See Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (amendment operated as a disclaimer of abandonment of subject matter).

The Panel Decision contravenes exactly this policy. The Panel ignored record evidence demonstrating, over and over again, that the higher phospholipid content used in Dey's surfactant was foreseeable, disclosed and surrendered by the '839 patent. The '301 patent claimed a phospholipid range that included the range Abbott found in Dey's product. In prosecuting the '301 patent, Abbott had retreated from the prior art by arguing that patentability was predicated on the importance of the ranges specified by the claims. (JA2366-JA2367.) In the '839 patent, the range of phospholipids was further constrained to avoid the prior art of the '301 patent. In the district court, Abbott attempted to prove that the upper range of phospholipids essentially was irrelevant up to 99.5% — an argument correctly rejected by that court because it contravenes this Court's ruling in *Warner-Jenkinson* that the

doctrine of equivalents should not be applied in a manner that vitiates any element of the claim. *Warner-Jenkinson*, 520 U.S. at 29.

Moreover, the '839 patent disclosed a higher range in the specifications, but did not claim it. (*See* Example 3, JA1124.) As this Court has explained, "While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly . . . claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention." *United States v. Adams*, 383 U.S. 39, 48-49 (1966) (citations omitted). *See also Watts v. XL Sys. Inc.*, 232 F.3d 877, 882 (Fed Cir. 2000) ("One purpose for examining the specification is to determine if the patent holder has limited the scope of the claims."). The Panel Decision ignored the limiting language in the specification of the '839 patent. This is what *Festo*, *Warner-Jenkinson*, *Johnson* and *Sage* forbid.

III. Certiorari Should be Granted Because The Decision Below Upsets The Delicate Balance Between A Patent Holder's Right to Protect Its Monopoly And The Public's Right to Innovate And Compete

1. Both *Festo* and *Warner-Jenkinson* warned against overly broad application of the doctrine of equivalents, emphasizing that it should not be used to undercut the definitional or public-notice functions of patents. *See Festo*, 122 S. Ct. at 1837-38; *Warner-Jenkinson*, 520 U.S. at 28-29; *see also Burns v. Meyer*, 100 U.S. 671, 672 (1879) ("The courts . . . should be careful not to enlarge, by construction, the claim which the Patent Office had admitted, and which the patentee has acquiesced in, beyond the fair interpretation of its terms."). The goal of both decisions was to protect a

patent holder's carefully drafted claim against infringement by an unforeseen equivalent, and at the same time prevent a patent holder from opportunistically recapturing foreseen, but unclaimed subject matter.

The Panel Decision, on the other hand, runs counter to the goals of our patent system as explained by this Court. A bedrock principle of patent law is that the claims define the scope of patent protection. *See, e.g., Aro Mfg. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("[T]he claims made in the patent are the sole measure of the grant. . . ."); *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) ("[T]he claims measure the invention."); *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935) ("Under the statute it is the claims . . . which define the invention. . . . None . . . can be aided by reading into it parts of the specifications, or of other claims, which the patent holder failed to include within it."); *Forest Laboratories*, 239 F.3d at 1312 ("The claims are the claims."). The claims give notice to the patent examiner of what he needs to evaluate for patentability, and they give notice to the public of what the patent holder owns and does not own.

As this Court said in *Warner-Jenkinson* and *Festo*, the patent holder is in the best position to define his claims with precision. He knows the function, way and result of each element of his invention. He knows (or the patent examiner tells him) what the prior art is. There is no one as skilled in his particular invention as he, and no one as interested in securing the broadest monopoly possible. Article 8 of our Constitution, as implemented by the patent laws, grants him a monopoly for a limited number of years for the patentable claims that he drafts. Those are the settled expectations of inventors, the patent office and the public. They go no further.

2. The Panel Decision threatens to circumscribe the doctrine of estoppel in a manner not anticipated by this Court or the patent bar. Claim construction will have no meaning if claims may be freely construed to encompass subject matter that a patent holder expressly disclosed and surrendered in carefully drafting his claims. A competitor, having examined specifications in an existing patent that disclose and surrender subject matter, will be surprised to find out subsequently that a product he worked so hard to bring to market is claimed to infringe the patent previously examined. Patent holders will not view their patents as defining what they own, but only as starting points for extending their patent monopolies. And the public will be confused, because a patent no longer gives notice of what the patent holder owns and what he does not.

CONCLUSION

For the reasons set forth above, this Petition should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED APRIL 23, 2002

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

01-1374

ABBOTT LABORATORIES and
MITSUBISHI-TOKYO PHARMACEUTICALS, INC.
(formerly known as Tokyo Tanabe Co., Ltd.),

Plaintiffs-Appellants,

v.

DEY, L.P. and DEY, INC.,

Defendants-Appellees.

DECIDED: April 23, 2002

Before NEWMAN, GAJARSA, and PROST, *Circuit Judges*.

PROST, *Circuit Judge*.

Plaintiffs Mitsubishi-Tokyo Pharmaceuticals, Inc. and Abbott Laboratories appeal the decision of the United States District Court for the Northern District of Illinois granting defendants Dey L.P. and Dey, Inc. summary judgment of noninfringement of U.S. Patent No. 4,397,839 ("the '839 patent"). Because the district court improperly precluded plaintiffs from relying on the doctrine of equivalents to prove infringement, we vacate the judgment of noninfringement and remand for further proceedings in accordance with this opinion.

Appendix A

BACKGROUND

I

Tokyo Tanabe Company, Ltd., now known as Mitsubishi-Tokyo Pharmaceuticals, Inc., and its exclusive United States licensee, Abbott Laboratories, (collectively "Abbott") sued Dey, L.P. and Dey, Inc. (collectively "Dey") for infringement of the '839 patent and U.S. Patent No. 4,338,301 ("the '301 patent"). These patents relate to a lung surfactant composition for treating respiratory distress syndrome in premature babies. The '301 patent, filed on May 21, 1980, represents the work of Drs. Fujiwara, Tanaka and Takei in developing a surfactant having the desirable properties of rapid spreading in the lungs and of reducing ultra-alveolar surface tension. Claim 1 of the '301 patent reads as follows:

> Surface active material containing phospholipid, neutral lipid, total cholesterol, carbohydrate, protein and water, which material is obtained from lung tissue of a mammal with or without further phospholipid, characterized in that *the phospholipid content is 75.0-95.5%*, the neutral lipid content is 1.8-14.0%, the total cholesterol content is 0.0-3.0%, the carbohydrate content is 0.1-1.5%, the protein content is 0.5-5.0% and water content is 1.7-6.0%, all based on the dried weight of said material, the minimum and maximum surface tension ranges of the material estimated by Wilhelmy's method wherein the material is added dropwise to the surface of physiological saline in an amount of 0.3-0.8 μg

> per square centimeter of surface area thereof being 2.1-8.6 dynes/cm and 48.2-58.0 dynes/cm when surface areas are 21.0 cm^2 and 45.6 cm^2 respectively.

'301 patent, col. 17, l. 59 col. 18, l. 6 (emphasis added).

The '301 patented surfactant was based on a composition labeled "TA-546." Dr. Tanaka, one of the three inventors of the '301 patent, "continued confirmatory studies on TA-546" and "discover[ed] that several important properties (i.e., surface tension-reducing capacity, spreadability over a liquid surface, and adsorbability to a gas-liquid interface) of TA-546 can be enhanced *by increasing the relative amount or content of free fatty acids* to 1.0-27.7% based on the total weight of TA-546." '839 patent, col. 1, ll.36-44 (emphasis added). TA-546 contained less than 1.0% free fatty acid, although the '301 patent makes no mention of this fact. *Id.* at col. 1, ll. 37-38; '301 patent, col. 5, Table I. Dr. Tanaka's discovery of the benefits of adding free fatty acids led him to file a new patent application on March 4, 1982, four months before the '301 patent issued on July 6, 1982. This new application issued as the '839 patent on August 9, 1983. Claim 1 of the '839 patent reads:

> A surface active material comprising (1) phospholipid, neutral fat, total cholesterol, free fatty acids, carbohydrate, protein and water, all of which are obtained from the lung tissue of a mammal, and (2) optionally at least one additional component selected from the group consisting of a phosphatidylcholine, a neutral fat and a free fatty acid, characterized in that *the overall phospholipid*

Appendix A

> *content is 68.6-90.7%*, the overall neutral fat content is 0.3-13.0%, the total cholesterol content is 0.0-8.0%, *the overall free fatty acid content is 1.0-27.7%*, the carbohydrate content is 0.1-2.0%, the protein content is 0.0-3.5%, and the water content is 2.1-5.2%, all based on the dry weight of the material, the surface tension of the material as measured at 15°-25° C. by Wilhelmy's method in which the material is added dropwise to the surface of physiological saline in an amount of 0.3-0.8 μg per square centimeter of the surface area thereof being 30.1-47.5 dynes/cm when the surface area is 54.0 cm^2.

'839 patent, col. 17, ll. 13-31 (emphases added).

The application for the '839 patent was filed as a separate and independent application — not as a continuation, divisional or continuation-in-part of the '301 application, even though the '301 application was pending at the time the '839 application was filed, and the applications shared common subject matter, a common inventor, and the same assignee. The same examiner also examined both the '839 and '301 applications. He initially rejected the pending claims of the '301 patent as being, among other things, prima facie obvious in light of three prior art articles. March 17, 1981 Examiner's Action at p. 2. In response to this rejection, the applicants argued as follows:

> The inventors of the invention covered by this application have studied the suggestions of these three references and discovered, through experimentation, that *only a surface-active*

> *material having the chemical composition claimed and disclosed at Table I at page 4 of the application under the heading "Composition of the Material" have the property of rapid spreading and of ultra-alveolar surface tension reduction.* The results obtained are caused by the particular and novel surface-active agent isolated, the method of using this agent on the ailment HMD, and the method of isolating the particular surface-active material.
>
> Accordingly, it is believed all of the claims define a patentable invention over the cited references, whether these references are taken separately or in combination.

July 1, 1981 Amendment at pp. 8-9 (emphasis added). After issuing a final rejection based on 35 U.S.C. § 112, ¶¶ 1 and 2, which was overcome by a September 3, 1981 Amendment After Final Rejection, the examiner issued a notice of allowance on December 17, 1981.[1]

The '839 application was filed on March 4, 1982, approximately three months after the examiner allowed the claims of the '301 application but before the '301 patent had issued. The examiner allowed the claims of the '839 application "because this application is an improvement over previously allowed patent claims; and no prior art was found which anticipates or makes obvious the instant claims."

---

1. While the claims were amended and arguments presented to the examiner, the substance of the Amendment After Final Rejection is not significant to our analysis in this case.

Appendix A

The '839 and '301 patents have been involved in prior litigation before our court. In *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305, 57 USPQ2d 1794 (Fed. Cir. 2001), this court considered whether the district court erroneously granted Forest a judgment of noninfringe-ment as a matter of law following a jury verdict of infringement. We affirmed the district court's decision because the jury's verdict was not supported by substantial evidence. Abbott failed to present any evidence that the accused products met the water limitation of the claims either literally or under the doctrine of equivalents. *Id.* at 1312-13, 57 USPQ2d at 1799-1800. We also stated that the above quoted argument from the '301 prosecution history was "an unmistakable assertion made to the PTO in support of patentability. . . . Accordingly, [Abbott] is estopped from asserting that the percentage of water in the surface active material is irrelevant." *Id.* at 1314, 57 USPQ2d at 1800.

II

Abbott began marketing the drug Survanta® in 1991 pursuant to its exclusive license under the '301 and '839 patents. Prior to the advent of Survanta®, neonatal respiratory distress syndrome had been a leading cause of death among premature infants. On November 19, 1999, Dey obtained approval from the United States Food and Drug Administration to market the surfactant Curosurf®. Curosurf® is manufactured in Italy by Chiesi Farmaceutici S.p.A. and imported and offered for sale in the United States by Dey. Dey first began offering Curosurf® for sale in the United States on February 14, 2000.

Appendix A

Abbott sued Dey on March 21, 2000, for infringement of the '301 and '839 patents, seeking damages and a preliminary and permanent injunction prohibiting Dey from using, selling or offering Curosurf® for sale in the United States. Dey counterclaimed for a declaratory judgment of noninfringement and invalidity. On May 19, 2000, Abbott formally moved for a preliminary injunction based only on the '839 patent, because the '301 patent expired six days later on May 25, 2000. Beginning on July 6, 2000, the district court held an evidentiary hearing on Abbott's motion. Abbott attempted to prove infringement under the doctrine of equivalents, conceding that Curosurf® did not literally meet claim 1's limitation of 68.6% 90.7% phospholipid. Abbott's tests of the Curosurf® paste found that one sample contained 91.8% phospholipid while another sample contained 94.5% phospholipid. Abbott presented expert testimony that the phospholipid content of Curosurf® was insubstantially different from the phospholipid component of the claimed surfactant because "95 percent [phospholipid] would work exactly the same" as the claimed phospholipid amount. Abbott's expert also testified that "it really doesn't matter whether it is 80 or 85 or 90 or 95 or probably even 99. As long as you have enough phospholipids to get to make this a monolayer, and they are in great excess, it really doesn't matter terribly what the composition is."

On July 26, 2000, the district court denied Abbott's motion for a preliminary injunction. *Abbott Labs. v. Dey, L.P.*, No. 00-C-1725 (N.D.Ill. July 26, 2000) (the "July 25th Order"). While the court concluded that Abbott "introduced evidence sufficient to show that the phospholipid in Curosurf® performs substantially the same overall function

as the phospholipid in the surface active material claimed in the '839 patent, and it does so in substantially the same way to obtain substantially the same overall result as the surface active material claimed in the '839 patent," the court precluded Abbott from relying on the doctrine of equivalents. *Id.* at 4-5. The court reasoned as follows:

> Because the '839 patent was issued as an improvement over a prior claimed invention, it is not entitled to the broad range of equivalents it might be if it was a pioneer patent instead; only a more restricted, narrow range of equivalents is available. The plaintiffs made no effort to narrow the range of equivalents available on the phospholipid element; instead they offered testimony suggesting that a phospholipid percentage as high as 99.99% would have functioned in the same way, effectively and improperly reading out the phospholipid range limitation altogether.

Id. at 5 (citations omitted). The court also denied the motion for a preliminary injunction because it believed that a "hypothetical claim" that literally contained a range of phospholipid up to 94.5% would not have been allowed over the prior art '301 patent. *Id.* at 6-7.

Abbott appealed the July 25th Order to our court. The parties had fully briefed the appeal and were preparing for a June 7, 2001, oral argument when the district court granted Dey summary judgment of noninfringement. *See Abbott Labs. v. Dey, L.P.*, No. 00-C-1725 (N.D. Ill. May 21, 2001) (the "May 21st Order"). We then granted a

motion to dismiss Abbott's appeal without prejudice to the parties raising the same issues in an appeal of the district court's summary judgment of noninfringement.

In its opinion granting summary judgment of noninfringement, the district court concluded that "a competitor would reasonably believe, based on the specification and claims of the '839 patent, and the prosecution history of the '301 patent, that the patentee relinquished the right to exclude any surface active material containing, among other things, more than 90.7% phospholipid based on dry weight." *Id.* at 4. With respect to how the claims of the '839 patent contributed to such an estoppel, the district court reasoned that

> the patentee chose to include specific percentage ranges for each chemical component in the surface active material, and by doing so he created a record that fairly notified the public that he was surrendering the right to exclude material comprised of even the same components in different percentages. The plaintiffs cannot recapture that surrendered subject matter through the doctrine of equivalents; nor can they recapture through the doctrine of equivalents the higher phospholipid percentage surrendered from the '301 patent with the issuance of the '839 patent.

Id. at 5. Regarding the preclusive effect of the specification, the district court stated that

> the patentee unequivocally disclosed in the specification of the '839 patent that the chemical composition set out in the patent — like the

> chemical composition set out in the '301 patent — was significant and that the changes made in that composition (specifically the increase in free fatty acids and the necessary corresponding decrease in one or more of the other components of the material) were similarly significant. The plaintiffs should not now be able to argue that those percentage ranges place no limit on their right to exclude competitors' products. . . .

Id. at 4-5.

With respect to whether the prosecution history of the '301 patent contributed to the estoppel, the district court admitted that it had "no authority for the proposition that the prosecution history of one patent is controlling when analyzing an estoppel claim related to another patent." *Id.* Nevertheless, the district court felt that "at least in this case, where the patent-in-suit discloses an improvement of the product and process disclosed in the earlier patent, consideration of the earlier patent's prosecution history makes good sense." *Id.*

Abbott appeals the district court's summary judgment of noninfringement of the '839 patent. The only claims at issue are independent claim 1 and its dependent claims 9 and 12-15. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

This court reviews a grant of summary judgment *de novo*, drawing all reasonable factual inferences in favor of the non-moving party. *See, e.g., Anderson v. Liberty Lobby, Inc.*,

477 U.S. 242, 255 (1986). Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Id.* at 247-48. The various legal limitations on the application of the doctrine of equivalents are to be determined by the court as a matter of law. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

Abbott argues that the district court's summary judgment should be reversed because the district court improperly precluded Abbott from relying on the doctrine of equivalents to prove infringement. According to Abbott, the district court: (1) impermissibly relied on the prosecution history of the '301 patent to create an estoppel with respect to the '839 patent; (2) performed an erroneous hypothetical claim analysis by failing to compare the hypothetical claim as a whole to the prior art; (3) mistakenly interpreted Abbott's expert testimony as "vitiating" the phospholipid claim limitation; and (4) improperly limited the claims to their literal scope because the claims recite numeric ranges. We address each of these arguments in turn.

I

The first step in a prosecution history estoppel analysis is to determine which claim limitations are alleged to be met by equivalents. Then, the court must determine whether the limitations at issue were amended during prosecution of the patent. If they were not, amendment-based estoppel will not bar the application of the doctrine of equivalents. However, even if the claim limitation has not been amended, an argument-based estoppel may nevertheless arise based on statements

made by the applicant during prosecution. *See, e.g., Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979, 52 USPQ2d 1109, 1113 (Fed. Cir. 1999); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376-77, 50 USPQ2d 1033, 1036 (Fed. Cir. 1999). It is undisputed that the phospholipid limitation of claim 1 was not amended during prosecution of the '839 patent; thus, there can be no amendment-based estoppel with respect to this claim limitation. Nor have the parties identified any statements in the '839 prosecution history that allegedly give rise to an argument-based estoppel. Absent any basis for an estoppel in the prosecution history of the '839 patent, the district court relied instead on the prosecution history for the '301 patent.

In its discussion of prosecution history estoppel, the district court cited *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.* for the proposition that "[p]rosecution history estoppel precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter it relinquished — whether by amendment of claims or by arguments made to obtain allowance of claims — during the prosecution of its application." May 21st Order at 3-4. In *Pharmacia*, we also stated that in order to determine what subject matter an applicant surrenders during prosecution, we must ask "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Pharmacia*, 170 F.3d at 1377, 50 USPQ2d at 1036 (quoting *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457, 46 USPQ2d 1169, 1175 (Fed. Cir. 1998) (en banc)). *Pharmacia* further noted that "[w]e have also stated that the prosecution history should be objectively viewed from the perspective of one skilled in the art." *Id.* at n.21. The district

court concluded that "a competitor would reasonably believe, based on the specification and claims of the '839 patent, *and the prosecution history of the '301 patent*, that the patentee relinquished the right to exclude any surface active material containing, among other things, more than 90.7% phospholipid based on dry weight." May 21st at 4 (emphasis added).

Based in part on our opinion in *Forest Laboratories*, 239 F.3d at 1314, 57 USPQ2d at 1800, Dey argues that the applicant for the '839 patent surrendered any scope of equivalents by arguing during prosecution of the '301 application that "only a surface active material having the chemical composition claimed [by the '301 patent] has the property of rapid spreading and of ultra-alveolar surface tension reduction." We disagree that this statement creates an estoppel with respect to the '839 patent. The statement was merely a characterization of the particular composition claimed by the '301 patent and how it differed from the known prior art. The composition of the '839 patent is a different composition, defined by claims that the examiner concluded were patentably distinct from the claims of the '301 patent. In addition, given that the statement was made before the '839 patent was even filed, it is not unreasonable to conclude that the statement has no applicability to surfactants that might be characterized or discovered in the future.

We also believe that the relationship, if any, between the '839 and '301 patents is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent, as was done by the district court. *See Laitram Corp. v. Cambridge Wire Cloth*

Co., 863 F.2d 855, 862 n.16, 9 USPQ2d 1289, 1296 n.16 (Fed. Cir. 1989) (finding no estoppel between two commonly owned patents because the '949 "application was filed more than one year after the '141 patent issued"); *Sextant Avionique S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 836, 49 USPQ2d 1865, 1878 (Fed. Cir. 1999) (Smith, J., dissenting) ("We have never based a finding of prosecution history estoppel on a statement made by a different applicant during prosecution of an unrelated application, nor have we ever hinted that competitors should examine the file histories of applications other than the one in suit in order to determine the scope of equivalents that may be accorded the patent."); *cf. Elkay*, 192 F.3d at 979, 52 USPQ2d at 1113 (relying on statements made during prosecution of a first patent to construe the claim language of a second patent, wherein both patents were continuations from a common application and used similar claim language).

It is true that the '839 and '301 patents are commonly owned by Abbott, and the inventor of the '839 patent is one of the three inventors of the '301 patent. However, the '839 application was not filed as a continuation, continuation-in-part, or divisional application of the '301 application. These applications have no formal relationship and were presented to the patent office as patentably distinct inventions. *See In re Berg*, 140 F.3d 1428, 1435 n.7, 46 USPQ2d 1226, 1231 n.7 (Fed. Cir. 1998) (noting, in the context of considering a double patenting rejection, that two applications filed by the same inventor were "not related as by continuation, continuation-in-part, or divisional" and that filing such two separate applications implied "that each application is independent and patentably distinct"). The invention of the '839 patent was also based on the

continuing studies of Dr. Tanaka, as opposed to the earlier combined efforts of the three inventors of the '301 application. The specification of the '839 patent makes clear that Dr. Tanaka's independent and additional research led to the discovery of the improved surfactant described and claimed by the '839 patent. *See* '839 patent, col. 1, ll. 35-45. Under these circumstances, we do not see a basis for concluding that statements made about the characteristics of the surfactant claimed by the '301 patent should be attributed to the improved surfactant claimed by the '839 patent, simply because the applications had a common assignee, one common inventor, and similar subject matter. We therefore conclude that the above-quoted statements from the prosecution history of the '301 patent do not create an estoppel with respect to the '839 patent.

II

We next consider the district court's hypothetical claim analysis and whether the prior art limits the scope of equivalents of claim 1 of the '839 patent. The district court denied Abbott any range of equivalents on the basis that the '839 patent was an "improvement" of the '301 patent, instead of a pioneer patent. July 25th at 5. A pioneer patent by definition will have little applicable prior art to limit it, whereas an improvement patent's scope is confined by the existing knowledge on which the improvement is based. *See, e.g., Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1301, 50 USPQ2d 1900, 1907 (Fed. Cir. 1999) ("Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a

crowded art field."). However, the fact that a patent is an improvement patent does not automatically preclude application of the doctrine of equivalents. "That a claim describing a limited improvement in a crowded field will have a limited range of permissible equivalents does not negate the availability of the doctrine [of equivalents] *vel non*." *Warner-Jenkinson*, 520 U.S. at 27 n.4.

To determine the scope of the doctrine of equivalents in light of the prior art, a court can consider a "hypothetical claim" that literally recites the range of equivalents asserted to infringe. "The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art." *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684, 14 USPQ2d 1942, 1948 (Fed. Cir. 1990). In this case, the hypothetical claim would be claim 1 of the '839 patent with the phospholipid limitation changed to have a range of 68.6% to 94.5%. In order for this hypothetical claim to be anticipated, "a single, prior art document [must] describe *every element* of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282, 54 USPQ2d 1673, 1679 (Fed. Cir. 2000) (emphasis added). Likewise, to make the hypothetical claim obvious, the court must find that "the differences between the subject matter sought to be patented [i.e., the hypothetical claim] and the prior art are such that *the subject matter as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (1994) (emphasis added).

Appendix A

The district court erred by comparing only the phospholipid limitation of claim 1 to the '301 patent (the only prior art considered by the court), while ignoring other limitations of the claim. The '301 patent describes a phospholipid range of 75.0%-95.5%, which overlaps the hypothetical claim's range of 68.6%-94.5%. The district court therefore concluded that the asserted range of equivalents was too broad because it encompassed the prior art. We disagree because the '301 patent fails to disclose the claim limitation of free fatty acids in the amount of 1.0%-27.7%. In fact, the '301 patent does not make any reference to a surfactant containing free fatty acids, although the '839 patent acknowledges that TA-546 "contains less than 1.0% of free fatty acids." '839 patent, col. 1, l. 38. It was this discovery that TA-546 "can be enhanced by increasing the relative amount or content of free fatty acids" that distinguished the '839 surfactant from the one described by the '301 patent. *Id.* at ll.43-44. Thus, the '301 patent cannot anticipate the hypothetical claim that literally covers the accused device, because the '301 patent does not disclose each and every limitation of that claim. We also have no basis for concluding that Abbott's hypothetical claim would be obvious over the '301 patent. On the contrary, the addition of free fatty acids distinguished the surfactant claimed by the '839 patent from the surfactant described by the '301 patent. The addition of free fatty acids is no less significant with respect to the hypothetical claim and, on this basis, an examiner could have determined that the hypothetical claim was nonobvious. *See Wilson Sporting Goods*, 904 F.2d at 684, 14 USPQ2d at 1948.

A corollary to the district court's conclusion that Abbott's hypothetical claim would not have been allowed was the idea that increasing the amount of phospholipid

> necessarily required a corresponding decrease in one or more of the material's other components. Thus, the change in percentages and the ratio among various components must indeed have been significant to the patent examiner, and the Court has no reason to believe the claim would have been allowed without the alterations made to the percentage ranges of both free fatty acid and phospholipid.

July 25th at p. 7. It is true that if a hypothetical surfactant contained 99.9% phospholipid, the surfactant could not, as a matter of simple math, also contain the claimed element of at least 1.0% free fatty acid. However, for a surfactant such as Curosurf® having an upper limit of 94.5% phospholipid, the surfactant can still contain the remaining elements of the claimed surfactant within their specified ranges, including a free fatty acid component of at least 1.0%, which is not found in the '301 patent. Thus, a hypothetical claim with an upper limit of 94.5% phospholipid continues to distinguish over the '301 patent for the same reason as the originally drafted claim: the addition of free fatty acids in the claimed range of 1.0%-27.7%.

As can be seen from a proper application of a hypothetical claim analysis wherein the claim as a whole is compared to the prior art, the scope of equivalents asserted by Abbott is not so broad as to encompass the prior art before us. The prior art does not preclude Abbott from relying on the doctrine of equivalents to prove infringement.

Appendix A

III

The doctrine of equivalents "is not a license to ignore or erase structural and functional limitations of the claim." *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581, 37 USPQ2d 1365, 1373 (Fed. Cir. 1996) (quoting *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532, 3 USPQ2d 1321, 1324 (Fed. Cir. 1987)). The district court believed that Abbott "offered testimony suggesting that a phospholipid percentage as high as 99.99% would have functioned in the same way [as the claimed phospholipid], effectively and improperly reading out the phospholipid range limitation altogether." July 25th Order at 5.

Abbott's expert testified, however, that there is an upper limit to the acceptable amount of phospholipid:

> In my opinion, there is an upper limit. And we know that because pure lipids, when it was a hundred percent, didn't work, and we tried that in kids . . . and it was unsuccessful with pure phospholipids. We know that pure phospholipids don't move very fast. . . . So somewhere you need enough other material in there to allow the lipid molecules to move fast. And I know that, from my own experiments, somewhere between .5, .1 percent, even as low as .01 percent in some experiments of the protein would make these phospholipids able to make it to the surface. So a hundred percent would not be right, but very close to a hundred percent could still work. . . . 95 percent would work exactly the same.

Thus, while an exact number cannot be stated any more precisely than "less than 100%," an upper limit does exist. Abbott's expert also testified that 95% phospholipid, an amount relevant to the Curosurf® product accused of infringement, would be exactly the same as the claimed phospholipid. Although this testimony expands the upper limit beyond the range literally recited by the claim, it does not eliminate the upper limit altogether. In addition, Abbott only asserts an upper limit of 94.5%. An examination of what happens in the extreme outer ranges of phospholipid content is therefore irrelevant to the scope of equivalents asserted by Abbott.

Because Abbott's application of the doctrine of equivalents to a phospholipid upper limit of 94.5% does not eliminate the upper limit of phospholipid from the claim, Abbott should not be precluded on this basis from relying on the doctrine of equivalents in this case.

IV

As a further basis for precluding Abbott from relying on the doctrine of equivalents, the district court reasoned that "the patentee chose to include specific percentage ranges for each chemical component in the surface active material, and by doing so he created a record that fairly notified the public that he was surrendering the right to exclude material comprised of even the same components in different percentages. The plaintiffs cannot recapture that surrendered subject matter through the doctrine of equivalents." May 21st Order at 5.

Appendix A

The fact that a claim recites numeric ranges does not, by itself, preclude Abbott from relying on the doctrine of equivalents. For example, in *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 54 USPQ2d 1086 (Fed. Cir. 2000), the claim at issue was for a porcelain composition that recited numeric percentage ranges for each component of the composition. While this court agreed with the *Jeneric/Pentron* district court's claim construction that the claim language "indicates that the invention's chemical components should be limited to the precise ranges set forth therein," we also stated that "the district court will have the opportunity to adjudicate fully the merits of infringement under the doctrine of equivalents." *Id.* at 1381, 1384, 54 USPQ2d at 1089, 1091. Thus, while the numeric ranges limited the literal scope of the claims, we did not preclude Jeneric/Pentron from applying the doctrine of equivalents simply because the claim recited numeric ranges for the components of the claimed composition. Likewise, in *Forest Laboratories*, we applied the doctrine of equivalents to the water element of claim 1 of the '839 patent, which requires 2.1% 5.2% water. *See Forest Labs.*, 239 F.3d at 1313, 57 USPQ2d at 1800. We therefore do not find a basis for precluding Abbott from relying on the doctrine of equivalents simply because the claim recites numeric ranges for the components of the claimed surfactant.

Appendix A

CONCLUSION

For the foregoing reasons, we conclude that the district court erroneously precluded Abbott from relying on the doctrine of equivalents to prove infringement by Dey. We therefore vacate the district court's summary judgment of noninfringement and remand this case for further proceedings in accordance with this opinion.

VACATED and REMANDED.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED MAY 18, 2001

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Case No. 00 C 1725

ABBOTT LABORATORIES, MITSUBISHI-TOKYO PHARMACEUTICALS, INC. f/k/a TOKYO TANABE CO., LTD.,

Plaintiffs,

v.

DEY, L.P. and DEY, INC.,

Defendants.

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

On July 26, 2000 this Court found that the plaintiffs failed to demonstrate a likelihood that they would be able at trial to prove infringement literally or under the doctrine of equivalents and accordingly denied their motion for a preliminary injunction. *See Abbott Laboratories v. Dey, L.P.*, No. 00 C 1725, 2000 WL 1029198 (N.D. Ill. July 26, 2000). Today we let the other shoe drop and enter summary judgment for the defendants.

Appendix B

Defendants first filed their motion for summary judgment in late September 2000. At that time, because plaintiffs' appeal from the denial of their motion for preliminary injunction had been filed, the Court decided to defer briefing on summary judgment until after that appeal was decided. In hindsight, this was probably ill-advised; the case was in fact ripe for summary judgment, and it is no doubt preferable for the Court of Appeals to review a complete record as opposed to an interlocutory ruling. In early March of this year, defendants supplemented their motion for summary judgment. This caused the Court to rethink its decision to defer briefing, and when the parties appeared for a previously-scheduled status hearing in mid-March, the Court decided to follow the course it should have taken last fall: to proceed with briefing on summary judgment. The present decision may create a bump in the road in the determination of the already-pending appeal, but in the long run it will facilitate a complete resolution of this case.

The pertinent facts are not disputed. The plaintiffs hold the rights in two United States patents, one expired (U.S. Patent No. 4,338,301) and one live (U.S. Patent No. 4,397,839). The '301 patent disclosed in claim 1, the patent's only independent claim:

> [s]urface active material containing phospholipid, neutral lipid, total cholesterol, carbohydrate, protein and water, which material is obtained from lung tissue of a mammal with or without further phospholipid, characterized in that the phospholipid content is 75.0-95.5%, the neutral lipid content is 1.8-14.0%, the total cholesterol content is 0.0-3.0%, the carbohydrate content is 0.1-1.5%,

> the protein content is 0.5-5.0% and water content is 1.7-6 .0%, all based on the dried weight of said material . . ." U.S. Patent No. 4,338,301 at col. 17, lines 59-67.

The '839 patent was issued as an improvement over the '301 patent; the patent's specification states that "the present invention is concerned with the improvement of TA-546 [the surface active material disclosed in the '301 patent]. . . ." U.S. Patent No. 4,397,839 at col. 1, lines 46-47. Claim 1 of the '839 patent discloses:

> a surface active material comprising (1) phospholipid, neutral fat, total cholesterol, free fatty acids, carbohydrate, protein and water, all of which are obtained from the lung tissue of a mammal, and (2) optionally at least one additional component selected from the group consisting of a phosphatidylcholine, a neutral fat and a free fatty acid, characterized in that the overall phospholipid content is 68.6-90.7%, the overall neutral fat content is 0.3-13.0%, the total cholesterol content is 0.0-8.0%, the overall free fatty acid content is 1.0-27.7%, the carbohydrate content is 0.1-2.0%, the protein content is 0.0-3.5%, and the water content is 2.1-5.2%, all based on the dry weight of the material. . . . *Id.*, col. 17, lines 13-25.

The plaintiffs allege that Curosurf®, a lung surfactant product developed and manufactured by defendants' licensor, infringes claim 1 of the '839 patent; they also allege infringement of claims 9 and 12-15, though our decision on claim 1 is determinative since it is the only independent claim.

Appendix B

At a hearing on plaintiffs' preliminary injunction motion, the plaintiffs introduced evidence showing that the accused product, Curosurf® (actually the precursor or "paste"), contained a higher percentage of phospholipid than that claimed in the patent; one lot tested contained 95.4% phospholipid and another lot contained 91.8% phospholipid, both outside the 90.7% upper limit claimed in the patent. Based on this evidence, the Court finds that the plaintiffs cannot prove literal infringement. *See Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) ("To show literal infringement of a patent, a patentee must supply sufficient evidence to prove that the accused product or process meets every element or limitation of a claim.") (citations omitted). Thus, unless the plaintiffs can prove infringement under the doctrine of equivalents, Dey is entitled to judgment as a matter of law on the plaintiffs' infringement claim.

When infringement under the doctrine of equivalents is alleged, "two primary legal limitations on the doctrine 'are to be determined by the court either on a dispositive pretrial motion or on a motion for judgment as a matter of law at the close of evidence and after the jury verdict.' Those legal limitations are prosecution history estoppel and the 'all elements rule'." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 586 (Fed. Cir. 2000) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n.8 (1997)). Prosecution history estoppel precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter it relinquished-whether by amendment of claims or by arguments made to obtain allowance of claims-during the prosecution of its patent application. *Pharmacia & Upjohn Co. v. Mylan*

Pharmaceuticals, Inc., 170 F.3d 1373, 1376-77 (Fed. Cir. 1999). The test for determining what subject matter the patentee surrendered is objective; we ask "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id.* at 1377 (quoting *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1457 (Fed. Cir. 1998)). Here, the Court finds that a competitor would reasonably believe, based on the specification and claims of the '839 patent, and the prosecution history of the '301 patent, that the patentee relinquished the right to exclude any surface active material containing, among other things, more than 90.7% phospholipid based on dry weight.

The '839 patent's specification states that after obtaining the '301 patent the inventor continued to tinker with the surface active material disclosed therein and discovered that "several important properties (i.e., surface tension-reducing capacity, spreadability over a liquid surface, and adsorbabiity to a gas-liquid interface) of TA-546 [the surface active material disclosed in the '301 patent] can be enhanced by increasing the relative amount or content of free fatty acids [from less than 1.0%] to 1.0-27.7% based on the total weight of TA-546." *Id.*, col. 1, lines 36-45. In short, the patentee unequivocally disclosed in the specification of the '839 patent that the chemical composition set out in the patent-like the chemical composition set out in the '301 patent, *see Abbott Laboratories v. Dey, L.P.*, 110 F. Supp. 2d 667, 675 (N.D. Ill. 2000) (citing Application for U.S. Patent No. 4,338,301, Prosecution History at p. 79-80) — was significant and that the changes made in that composition (specifically the increase in free fatty acids and the necessary corresponding decrease in one or more of the other components of the

material) were similarly significant. The plaintiffs should not now be able to argue that those percentage ranges place no limit on their right to exclude competitors' products — which is essentially the position they took at the preliminary injunction hearing when they elicited testimony from their expert that a surface active material with a phospholipid content of up to 99.9% would behave the same as one with a phospholipid content within the range specified in the patent. If that were truly the case, one wonders why the patentee would ever have included the percentage ranges for the chemical components to begin with. The bottom line is this: the patentee chose to include specific percentage ranges for each chemical component in the surface active material, and by doing so he created a record that fairly notified the public that he was surrendering the right to exclude material comprised of even the same components in different percentages. The plaintiffs cannot recapture that surrendered subject matter through the doctrine of equivalents; nor can they recapture through the doctrine of equivalents the higher phospholipid percentage surrendered from the '301 patent with the issuance of the '839 patent. *See Festo*, 234 F.3d at 565; *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1252-54 (Fed. Cir. 2000) (subject matter clearly and unmistakably surrendered in statements made to the PTO cannot be recaptured through the doctrine of equivalents).

The plaintiffs argue-correctly-that Dey has cited no authority for the proposition that the prosecution history of one patent is controlling when analyzing an estoppel claim related to another patent. But at least in this case, where the patent-in-suit discloses an improvement of the product and

process disclosed in the earlier patent, consideration of the earlier patent's prosecution history makes good sense. Although the Court stated that it would be improper to simply lift out of context statements made to secure the '301 patent and impose them on the '839 patent, the Court did not hold and does not think it appropriate to hold that the prosecution history of the '301 patent was entirely off-limits.

For the reasons explained above, the Court finds that the plaintiffs are unable as a matter of law to prove infringement either literally or under the doctrine of equivalents. Dey's supplemental motion for summary judgment [69-1] is granted; the original motion [65-1] is dismissed as moot. The Clerk is directed to enter judgment in favor of the defendants.

Dated: May 18, 2001

s/ Matthew F. Kennelly
MATTHEW F. KENNELLY
United States District Judge

APPENDIX C — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED JULY 25, 2000

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Case No. 00 C 1725

ABBOTT LABORATORIES, MITSUBISHI-TOKYO PHARMACEUTICALS, INC. f/k/a TOKYO TANABE CO., LTD.,

Plaintiffs,

v.

DEY, L.P. and DEY, INC.,

Defendants.

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

In this patent case, Tokyo Tanabe Company, Ltd., now known as Mitsubishi-Tokyo Pharmaceuticals, Inc., and its exclusive United States licensee, Abbott Laboratories, have sued Dey, L.P. and Dey, Inc., for patent infringement. Tanabe and Abbott allege that a lung surfactant product developed and manufactured by Dey's licensor, infringes claims 1, 9 and 12-15 of U.S. Patent No. 4,397,839 (the '839 patent),

which covers an improvement on U.S. Patent No. 4,338,301 (the '301 patent). The plaintiffs moved for a preliminary injunction seeking to preclude Dey from offering its product, Curosurf®, for sale in the United States. In connection with plaintiffs' motion, the Court conducted an evidentiary hearing, and at the close of the plaintiffs' evidence, Dey moved for denial of the preliminary injunction.

For a patent owner to obtain a preliminary injunction against an alleged infringer, he must show: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm; (3) a balance of the parties' hardships in favor of injunction; and (4) no potential injury to an important public interest. *See, e.g., Jeneric/Pentron, Inc. v. Dillon Company, Inc.*, 205 F.3d 1377, 1380 (Fed. Cir. 2000) (citing *Hybritech Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1451 (Fed. Cir. 1988)). The likelihood of success and irreparable harm factors play a key role in the analysis, and a court may decline to issue the injunction if the patent owner fails to prove either of these. *Jeneric/Pentron*, 205 F.3d at 1380 (citing *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996); *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996)). To demonstrate a likelihood of success, the patent owner must show that, in light of the presumptions and burdens that will inhere at trial, it will likely prove that the accused product infringes its patents. *Bell & Howell Document Management Products Company v. Altek Systems*, 132 F.3d 701, 705 (Fed. Cir. 1997); *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). In deciding whether the patent owner has satisfied this factor, the court must determine whether the evidence shows that

the accused device is likely to fall within the scope of the claims, as construed by the court. *See Sofamor*, 74 F.3d at 1220.

Dey argues that the preliminary injunction motion should be denied because the plaintiffs, having put on all their evidence, have failed to demonstrate that they will likely prove that the accused product infringes, either literally or under the doctrine of equivalents, each and every element of claim 1 of the '839 patent. Tanabe and Abbott concede that they cannot prove Curosurf® literally infringes each and every element of claim 1, the only independent claim in the '839 patent. The evidence presented by the plaintiffs at the preliminary injunction demonstrates that this is so, and the Court so finds. Specifically, the Court finds that the plaintiffs cannot show that Curosurf® literally infringes the element of claim 1 that the surface active material consists of 68.6-90.7% phospholipid. The plaintiffs presented evidence sufficient to demonstrate that the surface active material used to make Curosurf® (what has been referred to throughout this case as the precursor or paste) literally falls within the ranges specified in the '839 patent for neutral lipids, cholesterol, carbohydrate, protein, free fatty acid and water.[1] But they could not do the same for phospholipid; the plaintiffs' testing showed that one lot of the Curosurf® paste contained 95.4% phospholipid and another lot contained 91.8%

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1. Although Dey has challenged the testing methodology used by the plaintiffs to support these findings, the Court finds that the plaintiffs have introduced evidence sufficient, at least for purposes of a preliminary injunction motion, to sustain their burden of demonstrating that the components other than phospholipid fall within the ranges claimed in the '839 patent.

phospholipid, both outside the 90.7% upper limit claimed in the patent. Because a party seeking to prove infringement must demonstrate that the accused product reads on each and every element of a claim, *see Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (citing *Lemelson v. United States*, 752 F.2d 1538, 1551 (Fed. Cir. 1985); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991)), the plaintiffs' literal infringement claim would fail as would the case, unless the plaintiffs are permitted to prove infringement of the phospholipid element of claim 1 under the doctrine of equivalents. Thus, the plaintiffs' ability to demonstrate a likelihood of success on the merits and, in turn, their ability to succeed in obtaining a preliminary injunction motion, hinge on whether as a matter of law a range of equivalents broad enough to include the phospholipid percentages found in the Curosurf® paste is available.[2]

"Infringement may be found under the doctrine of equivalents if an accused product 'performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed

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2. In its June 28, 2000 opinion, the Court ruled that a statement made during the prosecution of the '301 patent would bar the plaintiffs from using the doctrine of equivalents to exclude a wider range of phospholipid than that claimed in the '301 patent. At a telephone hearing held after that opinion was issued, the Court clarified that that statement could not simply be lifted out of context and attributed to the '839 patent application, which had not even been filed at the time the statement was made. Thus the prosecution history estoppel argument is not available with respect to the '839 patent, and the questions of whether and how the doctrine of equivalents applies to the '839 patent remained open going into the preliminary injunction hearing.

invention.' " *Wilson Sporting Goods Co. v. David Geoffrey & Associates*, 904 F.2d 677, 683 (quoting *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc), *cert. denied*, 485 U.S. 961 (1988). The doctrine requires that the accused product contain each limitation of the claim or its equivalent. *Jeneric/Pentron*, 205 F.3d at 1383 (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)). The phospholipid element of claim 1 of the '839 patent is the only element for which the plaintiffs seek to resort to the doctrine of equivalents, and the Court therefore focuses exclusively on this element for purposes of deciding Dey's motion. *See Warner-Jenkinson*, 520 U.S. at 30 (the doctrine "must be applied to individual elements of the claim, not the invention as a whole," and courts must "ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.").

At the hearing on plaintiffs' motion for a preliminary injunction, the plaintiffs introduced evidence demonstrating that a surface active material containing a percentage of phospholipid higher than that disclosed in the '839 patent — indeed as high as 99.5 or 99.99%, *see* Transcript of Proceedings from July 6, 2000, at 66-67, 138 — would behave the same as a surface active material containing a percentage within the range claimed in the patent. Based on this evidence, the Court finds that the plaintiffs introduced evidence sufficient to show that the phospholipid in Curosurf® performs substantially the same overall function as the phospholipid in the surface active material claimed in the '839 patent, and it does so in substantially the same way to obtain substantially the same overall result as the surface active material claimed in the '839 patent.

But does that necessarily mean that the phospholipid range plaintiffs may claim extends to the upper limit suggested by the plaintiffs' witness? The Court concludes that this is not the case, for two reasons. First, the '839 patent is an improvement patent, not a pioneer patent. The patent itself discloses that the claimed invention "is concerned with the improvement of TA-546 [the surface active material disclosed in the '301 patent] on the basis of the above described discovery [the discovery that surface tension reducing capacity and spreadability can be enhanced by increasing the relative amount or content of free fatty acids in TA-546 from something less than 1.0% to 1.0-27.7%], as well as the provision of a pharmaceutical composition useable in the treatment of RDS in adults and premature infants." U.S. Patent No. 4,397,839, col. 1, lines 39-50. Because the '839 patent was issued as an improvement over a prior claimed invention, it is not entitled to the broad range of equivalents it might be if it was a pioneer patent; instead, only a more restricted, narrow range of equivalents is available. *See Thomas & Betts Corp. v. Litton Systems, Inc.*, 720 F.2d 1572, 1580 (Fed. Cir. 1983). The plaintiffs made no effort to narrow the range of equivalents available on the phospholipid element; instead they offered testimony suggesting that a phospholipid percentage as high as 99.99% would have functioned in the same way, effectively and improperly reading out the phospholipid range limitation altogether. *See Warner-Jenkinson*, 520 U.S. at 29 (the doctrine of equivalents, even as to an individual element, should not be allowed such broad play as to effectively eliminate that element in its entirety); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1367 (Fed. Cir. 1999) (the doctrine of equivalents cannot be used to vitiate an element from the claim in its

entirety); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998) (if a theory of equivalence would vitiate a claim limitation, then there can be no infringement under the doctrine of equivalents as a matter of law).

Moreover, "there can be no infringement if the asserted scope of equivalency of what is literally claimed would encompass the prior art." *Wilson*, 904 F.2d at 683 (citing *Pennwalt*, 833 F.2d at 934; *Senmed, Inc. v. Richard-Allan Medical Industries*, 888 F.2d 815, 821 (Fed. Cir. 1989)). In other words, to the extent an asserted range of equivalents covers what is already in the public domain, that range is unavailable under the doctrine of equivalents. "[S]ince prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim." *Wilson*, 904 F.2d at 684. To determine whether prior art restricts the range of equivalents to what is literally claimed, the Court visualizes a hypothetical patent claim sufficient in scope to literally cover the accused product and then asks whether that hypothetical claim could have been allowed by the PTO over prior art. *See Wilson*, 904 F.2d at 684. In this case, that means the Court must ask whether a claim specifying a surface active material characterized in that the overall phospholipid content is 91.8% or 95.4% (the percentages found in the two lots of Curosurf® paste) would have been allowed over the prior art. The Court believes that a claim so written never would have been allowed by the PTO; certainly the plaintiffs have failed to demonstrate that a claim so written would have been allowed, and it is their burden to do so. *See Wilson*, 904 F.2d at 685 (the burden is on the party seeking to avail itself of the doctrine of equivalents to prove that the range of equivalents which it seeks would not ensnare

the prior art). To cover the phospholipid percentages found in the Curosurf® paste, the '839 patent would have had to adopt the phospholipid percentages claimed in the '301 patent (75.0-95.5%), and if this had been the case, the PTO would likely have disallowed the claim as clearly anticipated by the prior art. Indeed, allowing the plaintiffs to extend through the doctrine of equivalents the '839 patent's phospholipid range up to the now-expired '301 patent's phospholipid range would improperly extend the monopoly power granted the plaintiffs under the '301 patent.

Though the plaintiffs presented no evidence on this point at the preliminary injunction hearing, in a brief filed after the Court gave an in-court oral summary of its ruling on Dey's motion, they argue that claim 1 of the '839 patent would have been allowed even if written to include an upper phospholipid range of 95.5% because "[t]he basis for patentability of the '839 patent — the existence free fatty acid content — remains the same in the actual and hypothetical claims." Brief on Prior Art Limitation to the Doctrine of Equivalents and the '839 Patent, p. 3. This is somewhat misleading. It is true that the free fatty acid percentage range in the hypothetical claim would be the same as that in the actual claim. But the *existence* of free fatty acid in the surfactant material claimed in the '839 patent is not what made it unique; free fatty acid was present in TA-546, the surface active material disclosed in claim 1 of the '301 patent. What made the material disclosed in the '839 patent unique was the *increase* in the free fatty acid content over that found in the '301 patent. *See* U.S. Patent No. 4,397,839, col. 1, lines 36-50. That increase necessarily required a corresponding decrease in one or more of the

material's other components. Thus, the change in percentages and the ratio among the various components must indeed have been significant to the patent examiner, and the Court has no reason to believe the claim would have been allowed without the alterations made to the percentage ranges of both free fatty acid and phospholipid. Accordingly, the Court finds that the range of equivalents to which the plaintiffs are entitled on the phospholipid element of claim 1 of the '839 patent does not include the percentages found to exist in the Curosurf® paste.

Based on this finding and the other findings set forth in this opinion, the Court concludes that the plaintiffs have not demonstrated a likelihood that they will be able, at trial, to prove infringement literally or under the doctrine of equivalents. The Court therefore grants Dey's motion and denies Tanabe and Abbott's preliminary injunction motion. The case is set for status on October 16, 2000 at 9:30 a.m.

Dated: July 25, 2000

s/ Matthew F. Kennelly
MATTHEW F. KENNELLY
United States District Judge

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR PANEL REHEARING AND REHEARING EN BANC DATED JUNE 14, 2002

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

01-1374

ABBOTT LABORATORIES and
MITSUBISHI-TOKYO PHARMACEUTICALS, INC.
(formerly known as Tokyo Tanabe Co., Ltd.),

Plaintiffs-Appellants,

v.

DEY, L.P. and DEY, INC.,

Defendants-Appellees.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLEES, and a response thereto having been invited by the court and filed by the APPELLANTS,* and the petition for rehearing having been reerred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

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* The court allowed the Appellees to file a reply to the response.

Appendix D

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on June 21, 2002.

Circuit Judge SCHALL did not participate in the vote

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: June 14, 2002

Supreme Court U.S.
FILED
OCT 15 2002
OFFICE OF THE CLERK

(2)

No. 02-396

In the Supreme Court of the United States

DEY, L.P. AND DEY, INC.,

Petitioners,

v.

ABBOTT LABORATORIES AND
MITSUBISHI-TOKYO PHARMACEUTICALS, INC.
(FORMERLY KNOWN AS TOKYO TANABE CO., LTD.),

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

1. Given the particular product and process at issue here, did the patent's description of how to "make and use" the claimed invention expressly surrender and disclaim all of the individual elements of all of the raw materials and precursor compounds described at each intermediate stage of the production process, such that the patent-holder is estopped from relying upon the doctrine of equivalents to show that a product that may have an element in common with one of those raw materials or intermediate compounds infringes the patented invention?

2. Should this case be remanded for further consideration in light of this Court's recent decision in *Festo Corp.* v. *Shoketsu Kinzoku Kabushiki Co.*, 122 S. Ct. 1831 (2002), given that the *Festo* case does not conflict in any way with the Federal Circuit's decision in this case?

3. Is the decision below in conflict with an earlier decision of the Federal Circuit in holding that statements made during the prosecution of the '301 patent may not constitute prosecution history estoppel with respect to the '839 patent, which was submitted to the Patent and Trademark Office as an entirely separate patent application?

RULE 29.6 STATEMENT

Pursuant to Rule 29.6, Respondents inform the Court that Respondent Mitsubishi-Tokyo Pharmaceuticals, Inc.—formerly known as Tokyo Tanabe Co., Ltd.—merged with Welfide Corporation and changed its name to Mitsubishi Pharma Corporation ("MPC") on October 1, 2001. MPC is a publicly traded company whose shares are traded on the Tokyo Stock Exchange. More than 10% of MPC's shares are owned by Mitsubishi Chemical Corporation, the shares of which are also traded on the Tokyo Stock Exchange.

Respondent Abbott Laboratories has no parent corporation, and no publicly held company owns 10% or more of Abbott Laboratories' stock.

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STATEMENT OF THE CASE

At issue in this case are two unrelated patents – U.S. Patent Nos. 4,397,839 (the '839 patent) and 4,338,301 (the '301 patent) – both of which concern compositions used for the treatment of neonatal respiratory distress syndrome. The composition claimed in the '301 patent was discovered and patented by three Japanese scientists in the 1970s. It claims a "surface active material" obtained from mammalian lungs and enhanced with particular additives. One of the '301 inventors, Dr. Yuji Tanaka, later discovered that compositions like those in the '301 patent could be improved by having higher levels of free fatty acid. Dr. Tanaka's subsequent invention was claimed in the '839 patent application and was presented to the Patent and Trademark Office as a patentably distinct invention and not as a continuation of the '301 patent. Both the '301 and '839 patents were assigned to Tokyo Tanabe Co., Ltd. (now known as Mitsubishi Pharma Corporation) and were licensed to Abbott Laboratories.

Abbott Laboratories and Tokyo Tanabe Co., Ltd. (collectively "plaintiffs" or "plaintiff-respondents") later filed suit and sought a preliminary injunction against Dey, L.P. and Dey, Inc. (collectively "Dey") alleging that a surfactant product distributed and marketed by Dey infringed both patents. Following an evidentiary hearing, the district court denied the motion for a preliminary injunction. Pet. App. 30a-38a. Specifically, the court held that Dey's product infringed each element of Claim 1 of the '839 patent literally, except for the phospholipid element; the claims in the '839 patent specified a phospholipid level of between 68.6% and 90.7%, whereas the Dey product had more than 90.7% phospholipid. *Id.* at 32a-

33a.[1] As for that element, the court found that the phospholipid levels in Dey's product performed the same function, in the same way, and to achieve the same result as the phospholipid levels specified in the '839 patent—a conclusion that would ordinarily suggest a finding of infringement under the doctrine of equivalents. *Id.* at 34a. Nevertheless, the district court held that plaintiffs were estopped from asserting the doctrine of equivalents with respect to the phospholipid element. The court's ruling was based principally on its view that because the '839 patent was an improvement over the '301 patent and contained specific numerical ranges for each component, the claims in the '839 patent are entitled to only a narrow range of equivalents. *Id.* at 35a-36a. The court's ruling was also based on the view that a "hypothetical claim" that actually contained a range of phospholipid up to the level in Dey's composition would not have been allowed over the prior art '301 patent. *Id.* at 36a-38a.

Dey then filed a motion for summary judgment of noninfringement. The district court granted the motion. Pet. App. 23a. The district court held that plaintiffs were estopped from relying upon the doctrine of equivalents because "a competitor would reasonably believe, based on the specification and claims of the '839 patent, and the prosecution history of the unrelated '301 patent, that the patentee relinquished the right to exclude any surface active material containing, among other things, more than 90.7% phospholipid." *Id.* at 27a. In the district court's view, the prosecution history of the '301 patent was significant because, in the course of prosecuting that patent, the applicant had argued that "only a surface-active

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[1] Abbott's tests of Dey's product found that one sample contained 91.8% phospholipid while another sample contained 94.5% phospholipid. Pet. App. 7a.

material having the chemical composition claimed [by the '301 patent]" would be effective. *Forest Laboratories, Inc.* v. *Abbott Laboratories*, 239 F.3d 1305, 1314 (Fed. Cir. 2001). As for the reference to the contents of the '839 patent itself, the district court explained that the specification disclosed that Dr. Tanaka had begun his research by modifying the compound claimed in the '301 patent. According to the court, that reference and history made clear that the numerical percentage ranges in the '839 patent's claims were "significant" and that the changes Dr. Tanaka made to the percentage composition of the '301 patent "were similarly significant." Pet. App. 27a-28a.[2] On that basis, the court concluded that plaintiffs should not be permitted to use the doctrine of equivalents to claim infringement by a composition containing a phospholipid element outside the numerical ranges specified in the claims of the '839 patent.

On appeal, the Federal Circuit rejected the district court's reasoning and held that plaintiffs were not barred by prosecution history estoppel from relying upon the doctrine of equivalents with respect to the phospholipid element. The Federal Circuit took issue with the district court's reliance on the prosecution history of the '301 patent and concluded—based on the particular circumstances of this case—that "the relationship, if any, between the '839 and '301 patents is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent." Pet. App. 13a (citations omitted); see *id.* at 13a-15a. The court also rejected the district court's

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[2] The district court did not cite Example 3 of the '839 patent, nor did it hold that any portion of that patent's specification disclosed and expressly disclaimed an alternative formulation with greater than 90.7% phospholipid.

hypothetical claim/prior art analysis, found that the plaintiffs' expert testimony and reliance on the doctrine of equivalents did not completely vitiate the phospholipid element in the '839 patent, and concluded that the patent's use of specific numeric ranges for the various components did not foreclose the use of the doctrine of equivalents. Having vacated the district court's award of summary judgment to Dey, the Federal Circuit remanded the case for further proceedings.

Dey filed a petition for rehearing and suggestion for rehearing en banc, arguing *inter alia* that the panel's opinion was inconsistent with the Federal Circuit's recent en banc opinion in *Johnson & Johnston Assocs., Inc.* v. *R.E. Service Co.*, 285 F.3d 1046 (2002), as well as with that court's previous decision regarding these particular patents in *Forest Laboratories, Inc.* v. *Abbott Laboratories*, 239 F.3d 1305 (2001). The Federal Circuit denied the rehearing petition and declined to take the case en banc.[3]

Dey now seeks this Court's review on similar grounds, submitting a petition that depends in significant part on a factual proposition never adopted by either the district court or the Federal Circuit. Most of the arguments raised in the petition are based on the factual allegation that a compound with a phospholipid level greater than 90.7% was disclosed and "expressly disclaimed" in the specification of the '839 patent. *E.g.*, Pet. 2. Based on that allegation, Dey argues that the

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[3] Dey's petition for certiorari alternatively seeks a remand for further consideration in light of *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002). When *Festo* was handed down, however, Dey did not see fit to bring that case to the Federal Circuit's attention under Federal Rule of Appellate Procedure 28(j), even though the rehearing petition in this case had not yet been decided.

Federal Circuit's ruling effectively allows a patent holder to reclaim "expressly disclaimed" subject matter using the doctrine of equivalents, in supposed conflict with various decisions of both that court and this one. This "express disclaim[er]," Dey argues, may be found in Example 3 of the '839 patent, which describes the *process* of making the patented chemical composition. Dey contends that because one of the intermediate steps in the process involved a preliminary compound containing 92.8% phospholipid, the inventor thereby "disclosed and expressly disclaimed" a composition with more than 90.7% phospholipid as an alternative to the patented invention. Pet. 15. Accordingly, Dey argues that plaintiffs should not be able to rely upon the doctrine of equivalents with respect to the phospholipid element.

Neither the district court nor the Federal Circuit has accepted Dey's factual contention that the '839 patent "expressly disclaims[s]" an alternative composition with a phosopholipid level of more than 90.7%. Although the district court held that plaintiffs could not rely upon the doctrine of equivalents, it based that ruling on limited factors—namely, the prosecution history of the '301 patent, and the fact that the '839 patent was an improvement patent that specified a particular percentage range for each of the components in the composition. Neither the district court—nor the Federal Circuit in rejecting its conclusions—considered this to be a case where subject matter was "expressly disclaimed" in the specification of the patent itself. And neither court even mentioned Example 3 of the '839 patent, in which Dey now locates the alleged "express disclaime[r]" that is so critical to its current position.

REASONS FOR DENYING THE PETITION

Dey's primary argument in favor of certiorari—namely, that the decision below conflicts with several decisions of the

Federal Circuit and this Court—is based on a factual contention never adopted by either of the courts below. Dey repeatedly contends that the '839 patent "expressly disclaimed" any compound with a phospholipid level of more than 90.7%. Pet. 2, 15, 16. At this stage in the proceedings, however, neither the district court nor the Federal Circuit has accepted that factual characterization. Moreover, as set out below, plaintiffs strenuously dispute Dey's position that the patent "expressly disclaim[s]" phospholipid levels over 90.7%. Given the continuing dispute over this critical factual issue, this case does not truly pose the questions suggested by the petition, nor would it provide a good vehicle for resolving any issue relating to the use of the doctrine of equivalents in cases of express disclaimer.

Moreover, even if Dey's factual supposition were correct, there is no statement in any of the opinions below that could possibly create any conflict of precedent on the issue of whether the doctrine of equivalents is available in cases where a patent expressly disclaims some alternative to the claimed invention. The Federal Circuit's opinion does not mention or discuss Dey's argument that the '839 patent "expressly disclaimed" a compound with a certain phospholipid range, almost certainly because the argument was suggested at most as a sidelight to Dey's principal appellate argument and was obviously meritless, given the circumstances of this case. Regardless of the reason, however, the absence of any discussion on this subject in the decision below (or in the district court's opinions) means that the case will not stand as precedent for the proposition that the doctrine of equivalents is available for subject matter that is expressly disclaimed.

Dey has also failed to demonstrate a need for this Court's intervention in the Federal Circuit's interpretation of these

particular patents. The alleged conflict between the decision below and the decision in *Forest Laboratories, Inc.* v. *Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001), is illusory. In fact, the two decisions are readily reconcilable—and obviously were reconciled in the view of the Federal Circuit, which declined to grant rehearing or rehearing en banc even after Dey brought the alleged conflict to its attention. In any case, even if the two opinions did conflict, the issue of the relationship between these two particular patents is not a matter appropriate for a grant of certiorari.

I. The Petition Depends Upon A Factual Supposition Never Adopted By The Courts Below And Strenuously Disputed By Plaintiffs.

Most of the arguments offered in Dey's petition rest on the unproven factual supposition that the '839 patent expressly discloses and disclaims a phospholipid range greater than 90.7%. It is that characterization of the patent that creates the supposed conflict between the decision below and previous decisions of the Federal Circuit (Pet. 15, 16, 18), as well as the supposed conflict with decisions of this Court (Pet. 19, 22). Further, this factual supposition also forms the basis of Dey's argument that the decision below will have some negative effect on patent law generally. Pet. 24. This basic factual predicate to Dey's principal arguments remains highly disputed and has never been adopted or commented upon by the courts below. Under the circumstances, this case is singularly unworthy of certiorari.

A. The '839 Patent Did Not "Expressly Disclaim[]" Compositions With Higher Phospholipid Levels.

Dey's argument that the '839 patent "expressly disclaim[s]" compositions with higher levels of phospholipid is based upon

Example 3 of the '839 patent – a portion of the patent never cited or mentioned in any of the opinions below. See Pet. 15 (citing Example 3); *id.* at 18 (discussing Example 3 as the location of the "express disclaim[er]"); *id.* at 22 (same effect). Given the context of Example 3 and the nature of the particular compounds at issue, however, it is clear that the patent's Example 3 does not "expressly disclaim[]" anything.

The portion of Example 3 on which Dey relies so heavily clearly refers to a precursor residue containing 92.8% phospholipid that was derived at an intermediate stage in the production process, *not* to an alternative formulation that could substitute for the claimed invention. U.S. Patent No. 4,397,839 col. 13, ll. 15-35 (C.A. J.A. A1113, A1124). In Example 3, minced cattle lungs were combined with saline and filtered to obtain an extract. *Id.* at cols. 11-13 (C.A. J.A. A1123-A1124). The extract was then centrifuged, combined with other materials, and put through a number of further processes to obtain a solid residue, which happened to have a phospholipid content of 92.8%. *Id.* at col. 13, ll. 15-28. Three ingredients (one phospholipid and two neutral lipids) were then added to that solid residue, and the resulting mixture was suspended in distilled water and lyophilized. *Id.* at ll. 29-35. The final product had the chemical composition claimed in the '839 patent. *Id.* There is no evidence that the three added ingredients were intended to decrease the percentage content of phospholipid or to dedicate the higher percentage to the public; if that had been Dr. Tanaka's intent, he would not have included 11 grams of phospholipid among the added ingredients. See *id.* Equally (or more) plausible is the notion that Dr. Tanaka intended the added ingredients to bolster the neutral lipid content of the precursor, which (at 0.2%) was below the level claimed in the '839 patent.

Accordingly, the '839 patent never discloses or even hints that a composition with a phospholipid content of 92.8% might serve as an alternative to the claimed composition or that it could be used as a final product in the treatment of respiratory distress syndrome. Moreover, Example 3 of the patent does not describe any alteration of the claimed compositional ranges in order to preserve patentability. Given the true context of the cited reference in Example 3, there was obviously no surrender of equivalents, much less a "clear and unmistakable" surrender of the sort that can trigger estoppel. *KCJ Corp.* v. *Kinetic Concepts, Inc.*, 223 F.3d 1351, 1359 (Fed. Cir. 2000). Dey has cited no authority to support the view that the patentee of a particular chemical composition intentionally surrenders all precursor compounds and byproducts formed at intermediate stages merely by complying with the statutory requirement that mandates a complete description of how to "make and use" the invention. 35 U.S.C. § 112.

As this analysis shows, Example 3 of the '839 patent's specification does not "expressly disclaim" an alternative composition as Dey contends. For purposes of this petition, however, it is sufficient that the court below did not accept or even comment upon Dey's suggestion that an alternative composition was expressly disclosed and disclaimed. Without some discussion on this point, the opinion below does not conflict with any of the other decisions cited in Dey's petition.

B. The Alleged Conflicts Between The Decision Below And Other Federal Circuit Decisions Are Illusory.

Given that the Federal Circuit did not adopt (or even mention) Dey's position on this factual issue, there is no conflict between the decision below and the Federal Circuit's opinions in *Johnson & Johnston Assocs. Inc.* v. *R.E. Service Co.*, 285 F.3d 1046 (2002) (en banc), *Maxwell* v. *J. Baker, Inc.*,

86 F.3d 1098 (1996), and *Sage Products, Inc.* v. *Devon Indus., Inc.*, 126 F.3d 1420 (1997).

The *Johnson* case related to the manufacture of printed circuit boards, which are composed of sheets of copper foil layered with sheets of a nonconducting material. 285 F.3d at 1048. The patent claimed an assembly to aid in the manufacture of the boards by adhering the very fragile sheets of copper foil to a more substantial "substrate" sheet of aluminum. When the copper foil was attached to the substrate, workers could more easily handle it and could assemble the boards with minimal risk of damaging the foil. *Id.* at 1049. The patent's specification described the function of the substrate as follows:

> The use of the adhered substrate * * *, regardless of what material it is made of, makes the consumer's (manufacturer's) objective of using thinner and thinner foils and ultimately automating the procedure more realistic since the foil, by use of the invention, is no longer without the much needed physical support.

Id. at 1049-1050 (quoting U.S. Patent No. 5,153,050) (emphasis added). Although the patent claimed a substrate made of aluminum only, the specification clearly stated that other materials could be used just as effectively:

> While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys, may be used. In some instances * * * polypropelene [sic] can be used.

Id. at 1050 (quoting the '050 patent).

The critical feature of the patent in *Johnson* was that it expressly stated that an alternative composition would perform

in the same manner as the claimed composition. *Id.* ("'*other* metals * * * may be used'"); *id.* at 1049 (substrate would have the desired effect "'regardless of what material it is made of'"). The Federal Circuit relied on this statement in concluding that the patentee could not use the doctrine of equivalents to show that an assembly using a stainless steel substrate infringed the patent. *Id.* at 1055. Quoting the above description of the substrate's composition, the court explained that the patentee had "disclosed without claiming the steel substrates" and "cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel." *Id.*

The Federal Circuit followed the same analysis in *Maxwell*, which preceded and was reinforced in *Johnson*. In *Maxwell*—which concerned a system for attaching pairs of shoes together—the patentee disclosed that an alternative system would have performed the same function: though the patentee "limited her claims to fastening tabs attached between the inner and outer soles" of the shoes, she disclosed "alternatives in which the fastening tabs could be 'stitched into the lining seam of the shoes.'" 86 F.3d at 1108. By failing to claim these "alternate shoe attachment systems," the patentee "dedicated the use of such systems to the public." *Id.*; cf. *SciMed Life Sys., Inc.* v. *Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001) (patentee could not invoke doctrine of equivalents when patent specifically identified and criticized the alternative device that allegedly infringed).

The basic factual predicate to Dey's arguments based on these cases is simply wrong—or at least unproven and never adopted by the courts below. Unlike in *Johnson* and *Maxwell*, the opinion below does not hold or suggest that the '839 patent expressly disclaims an alternative to the claimed composition.

Indeed, as discussed above, Example 3 of the '839 patent does not even hint that the precursor compound derived at a preliminary stage of the production process could actually be used in the treatment of a human infant. On the contrary, under Example 3, additional materials had to be added to the precursor product before it would become a final, useable product. The patent's specification properly set forth in detail both the composition of the precursor material and the manner in which the final composition was obtained. This kind of discussion is fundamentally different from the express disclosure of an *alternative* to the claimed composition, as found in *Johnson* and *Maxwell*. At a minimum, given the absence of any factual finding that the patent "expressly disclaim[s]" a compound with a higher level of phospholipid, there is no conflict between the decision below and the settled law of the Federal Circuit.

In arguing for rehearing before the Federal Circuit, Dey contended that *Johnson* and *Maxwell* cannot be limited to cases where the patent expressly discloses an "alternative" to the claimed invention, because that reading would represent a return to the principles set out in *YBM Magnex, Inc.* v. *International Trade Comm'n*, 145 F.3d 1317 (Fed. Cir. 1998), which *Johnson* expressly overruled. That is nonsensical. To say that a patent "discloses" and fails to claim a different composition necessarily means that the patent must disclose it *as an alternative* to the claimed invention.[4] The en banc court

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[4] In addition, to the extent that a subject matter disclosed but unclaimed by a patent is "dedicated" to the public under *Johnson*, a third party would be entitled to practice a similar invention only if it is exactly the same composition as the one disclosed and left unclaimed. Dey distorts this notion by suggesting that the '839 patent dedicates one individual *element*—a phospholipid level—in

in *Johnson* was critical of *YBM Magnex* for a different reason: it characterized *YBM Magnex* as incorrectly attempting to limit *Maxwell*'s preclusion on the doctrine of equivalents "to situations where a patent discloses an unclaimed alternative *distinct from the invention*." 285 F.3d at 1052 (emphasis added); see also *YBM Magnex*, 145 F.3d at 1320 (describing *Maxwell* as precluding reliance on the doctrine of equivalents because of "the distinctness of the two embodiments" described in the specification). Thus, the error in *YBM Magnex* stemmed from its conclusion that reliance on the doctrine of equivalents is precluded only where the disclosed alternative is markedly "distinct from" the claimed invention. By overruling *YBM Magnex* in *Johnson*, the Federal Circuit made clear that the doctrine of equivalents is unavailable whenever a patent expressly discloses and fails to claim an alternative to the claimed invention, whether "distinct" or not. Nothing in *Johnson* suggests that the doctrine of equivalents would be barred in the instant case, where the court below did not find or mention any express disclosure of an alternative to the claimed invention (and where, in fact, there was no such disclosure).

Further, the panel in this case was well aware of *Johnson* both during oral argument and at the time of its decision, even without briefing by the parties. *Johnson* was argued to the Federal Circuit en banc on October 3, 2001 and was decided less than one month before the decision here was rendered. The *Johnson* case was obviously an important case in the Federal Circuit, as it resolved an apparent tension between two previous

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isolation, apart from any other components of the composition. In fact, Dey's own composition is *not* the same in all respects as the precursor compound described in Example 3 of the '839 patent. It does not even have the same 92.8% level of phospholipid that is contained in the precursor compound. See *supra* at 1 n.1.

decisions by overruling one of them. Two of the three panel judges in this case (including the author of the panel opinion) joined the per curiam opinion for the court in *Johnson*. The third panel member (Judge Newman) dissented from the court's opinion in *Johnson* with an extensive written opinion. Clearly, when the panel issued its opinion here, all three members of the panel were well aware of how the en banc court had resolved the *Johnson* matter. Thus, it is not surprising that the panel's decision is entirely consistent with *Johnson*.[5]

Dey also claims that the decision below is in conflict with *Sage Products, Inc.* v. *Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997). Dey characterizes that case as holding that the doctrine of equivalents is unavailable for any subject matter that would have been foreseeable at the time of filing and could have been claimed in the patent by one skilled in the art. Even accepting that characterization, there is no conflict with the decision below. At this stage in the proceedings, there has been no factual finding that a skilled patent drafter would have foreseen that a composition with a higher level of phospholipid could have been used effectively in the treatment of human infants. To the extent that Dey is basing its "foreseeability" argument on the patent's supposed "express disclaimer" of higher phospholipid levels in Example 3, that proposition is at best unproven and at worst flatly wrong. Thus, there is no real conflict with *Sage Products*.

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[5] Furthermore, in its petition for rehearing and suggestion for rehearing en banc, Dey fully briefed the *Johnson* case and gave both the panel and the full Federal Circuit the opportunity to address any possible conflict between that case and the decision below. Dey's rehearing petition was denied, and the full court declined the suggestion to rehear the case en banc.

C. Dey Has Not Identified Any Inconsistency Between The Decision Below And Previous Decisions Of This Court.

Dey also seeks certiorari on the ground that the Federal Circuit's decision "disrupts the expectations" created by this Court's most recent decisions on the doctrine of equivalents: *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002), and *Warner-Jenkinson Co.* v. *Hilton-Davis Chemical Co.*, 520 U.S. 17 (1997). Pet. 19; see also *id.* at 22-24. Dey even argues that the decision below should be remanded for further consideration in light of *Festo*, which was handed down after the Federal Circuit's decision in this case. Pet. 11. Once again, however, these arguments rely heavily on Dey's factual supposition that in this case the alleged equivalent "was foreseeable, disclosed and surrendered" by the '839 patent. Pet. 21; see also *id.* at 22 (asserting that the '839 patent disclosed and failed to claim a higher range of phospholipids and citing Example 3); *id.* at 24 (arguing that claim construction "will have no meaning" if the doctrine of equivalents can be used "to encompass subject matter that a patent holder expressly disclosed and surrendered").[6] As explained above, the factual predicate to these arguments was

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[6] In this context, Dey also relies on the prosecution history of the '301 patent, arguing that the patent holder retreated from the prior art by arguing the importance of the specific percentage ranges described in that patent's claims. Pet. 21. As the Federal Circuit properly held, however, "the relationship, if any, between the '839 and '301 patents is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent." Pet. App. 13a.

never adopted by the courts below and is strenuously disputed by plaintiffs.[7]

As for *Festo*, the petition does not attempt to identify any specific conflict or tension with the opinion below but merely attributes to *Festo* the view that the doctrine of equivalents should not be used too broadly. Pet. 19-24.[8] Dey also describes a parade of horribles that it concludes will follow from the decision below. *Id.* at 24. If the '839 patent did *not* "expressly disclose and surrender" the relevant subject matter, however, then even Dey would have to concede that there is no parade of horribles. Given the continuing dispute over that factual proposition and the complete absence of a finding by the court below that the patent expressly disclosed the relevant subject matter, Dey's argument loses any force it might conceivably have.

Dey also suggests that the decision below conflicts with *Warner-Jenkinson*'s warning that the doctrine of equivalents should not be used to eliminate an element in its entirety. Pet.

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[7] Dey may argue that the Federal Circuit's failure to address Example 3 and the alleged "express disclaim[er]" is itself error that requires correction. In plaintiffs' view, however, the absence of this argument from the published opinion simply reflects the argument's obvious lack of merit and the fact that it was offered as (at most) a side-light to Dey's principal argument on appeal—namely, that the prosecution history of the '301 patent and the relationship between the two patents precluded application of the doctrine of equivalents. In any event, this sort of error would not be worthy of a grant of certiorari.

[8] Dey ignores the fact that *Festo* significantly *expanded* the availability of the doctrine of equivalents in cases of prosecution history estoppel. *Festo*, 122 S. Ct., at 1840-1842.

20 (citing 520 U.S. at 28-29). Under the facts of this case, however, there is no such conflict. The Federal Circuit specifically held, based upon the evidentiary record in this case, that plaintiffs' expert testimony and their reliance on the doctrine of equivalents did *not* vitiate the upper limit on phospholipids. Pet. App. 20a (although the expert testimony regarding the equivalence of the different levels of phospholipid effectively "expands the upper limit beyond the range literally recited by the claim, it does not eliminate the upper limit altogether"). Thus, there is no conflict between the decision below and *Warner-Jenkinson*.

II. The Alleged Conflict Between Two Federal Circuit Decisions Relating To The Patents At Bar Is Illusory And Does Not Merit This Court's Attention.

Dey's petition also asks this Court to resolve an alleged conflict between the decision below and the Federal Circuit's opinion in *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (2001), which also concerned the '301 and '839 patents. Pet. 16-17. According to Dey, the two decisions are in disagreement about whether statements made during the file history of the '301 patent can create prosecution history estoppel for the '839 patent. *Id.*

Dey's argument misstates the holding in *Forest Laboratories* and overstates the significance of the issue of prosecution history estoppel in that case. In *Forest Laboratories*, the Federal Circuit considered whether the district court had erroneously granted judgment of noninfringement of the '301 and '839 patents following a jury verdict to the contrary. The court affirmed the district court's decision on the ground that Abbott had failed to present any evidence that the accused products met the water limitation contained in both claims either literally or under the doctrine of

equivalents. 239 F.3d at 1312-1313. The court added that an argument made during the prosecution of the '301 patent (namely, that "only a surface-active material having the chemical composition claimed and disclosed" in the '301 application would have the desired therapeutic effect) led to the conclusion that plaintiffs were estopped from asserting that the percentage of water was irrelevant. *Id.* at 1314.

Significantly, however, the court in *Forest Laboratories* did not mention prosecution history estoppel with respect to the '839 patent specifically. The opinion's brief discussion of estoppel (which was *dicta* in any event) cited only the prosecution history of the '301 patent and thus provided an alternative ground for affirmance for that patent only. Dey's current reading of *Forest Laboratories* is strained indeed; given that Dey could cite no authority for the proposition that one patent's history can work an estoppel in an unrelated patent, it is extremely unlikely that the Federal Circuit would have adopted that novel argument and dramatically expanded the doctrine of prosecution history estoppel without explicitly stating that it was doing so.

In any case, because *Forest Laboratories* does not expressly discuss why or even whether it would have used the '301 patent's history as estoppel with respect to the '839 patent, any conflict with the decision here is illusory. The decision below carefully explains that under the facts of this case, any statements made in the prosecution of the '301 patent did not and could not limit the use of the doctrine of equivalents to show infringement of the '839 patent. Pet. 11a-15a. With no explicit holding or reasoning to the contrary, *Forest Laboratories* hardly constitutes conflicting precedent justifying a grant of certiorari.

Finally, even if Dey's reading of *Forest Laboratories* were correct, the relationship between the '301 and '839 patents is of very limited concern. As noted above, the Federal Circuit's analysis of the issue in this case turned on the specific facts and circumstances underlying these particular patents. Any lingering dispute about the relationship between these specific patents would not be worthy of this Court's attention.

CONCLUSION

The petition for certiorari should be denied.

Respectfully submitted.

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